

2001 ANNUAL REPORT ESRD CLINICAL PERFORMANCE MEASURES PROJECT

**OPPORTUNITIES
TO IMPROVE CARE FOR
ADULT IN-CENTER HEMODIALYSIS,
ADULT PERITONEAL DIALYSIS, and
PEDIATRIC IN-CENTER HEMODIALYSIS PATIENTS**

DECEMBER 2001



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Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Center for Beneficiary Choices
Baltimore, Maryland



Data on adult in-center hemodialysis patients are from October–December 2000

Data on adult peritoneal dialysis patients are from October 2000–March 2001

Data on pediatric in-center hemodialysis patients are from October–December 2000

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Note: The clinical data collected for the 2001 ESRD Clinical Performance Measures Project were from the time period of October–December 2000 for the adult in-center hemodialysis patients, October 2000–March 2001 for the adult peritoneal dialysis patients, and October–December 2000 for the pediatric in-center hemodialysis patients.

2002 Data Collection Effort

In 2002, we will again collect data for the ESRD Clinical Performance Measures on a national sample of adult in-center hemodialysis, adult peritoneal dialysis, and all pediatric in-center hemodialysis patients (≥ 12 and < 18 years old).

Any questions about the Project may be addressed to your ESRD Network staff or to members of the ESRD Clinical Performance Measures Quality Improvement Workgroup (APPENDICES 5 & 6).

Look for this report, as well as other ESRD Clinical Performance Measures Project and Core Indicators Project Reports, on the Internet at: www.hcfa.gov/quality/3m.htm

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- The eighteen ESRD Network Organizations throughout the United States (See Appendix 5).
- The following CMS Central Office staff: Diane L. Frankenfield, DrPH, Ava Marie Chandler, and Debbie Grossblatt.
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- The staff at more than 2,800 dialysis facilities in the United States who abstracted the requested information from medical records on more than 8,000 adult in-center hemodialysis, adult peritoneal dialysis, and pediatric in-center hemodialysis patients.
- The many other individuals in the renal community and CMS who contributed to this work.

ACRONYMS

List of Commonly Used Acronyms

AVF Arterial Venous Fistula

BCG Bromcresol Green Laboratory Method

BCP Bromcresol Purple Laboratory Method

BMI Body Mass Index

BSA Body Surface Area

BUN Blood Urea Nitrogen

CAPD Continuous Ambulatory Peritoneal Dialysis

CCPD Continuous Cycling Peritoneal Dialysis

CIP Core Indicators Project

CMS Centers for Medicare & Medicaid Services

CPM Clinical Performance Measure

CQI Continuous Quality Improvement

CrCl Creatinine Clearance

DOQI Dialysis Outcomes Quality Initiative

ESRD End-Stage Renal Disease

FSGS Focal and Segmental Sclerosis

GFR Glomerular Filtration Rate

HCFA Health Care Financing Administration

HCQIP Health Care Quality Improvement Program

HD Hemodialysis

Hgb Hemoglobin

IV Intravenous

Kt/V or Kt/V_{urea} Urea Clearance x Time normalized by total body water/the Volume of distribution of Urea

NIPD Nightly Intermittent Peritoneal Dialysis

NKF National Kidney Foundation

PD Peritoneal Dialysis

QA Quality Assurance

QI Quality Improvement

RRF Residual Renal Function

SC Subcutaneous

SD Standard Deviation

SLE Systemic Lupus Erythematosus

TCV Total Cell Volume

TSAT Transferrin Saturation

UKM Urea Kinetic Modeling

URR Urea Reduction Ratio

USRDS United States Renal Data System

I. EXECUTIVE SUMMARY

The ESRD Clinical Performance Measures (CPM) Project, now in its eighth year, is a national effort led by the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration, and its eighteen ESRD Networks to assist dialysis providers to improve patient care and outcomes. Since 1994 the project has documented continued improvements, specifically in the areas of adequacy of dialysis and anemia management. The providers of dialysis services are to be commended for their ongoing efforts to improve patient care.

The 2001 ESRD CPM Annual Report describes the findings of several important clinical measures and/or characteristics of a nationally representative random sample of adult (aged ≥ 18 years) in-center hemodialysis patients and peritoneal dialysis patients. New this year is the addition of findings for all in-center hemodialysis patients aged ≥ 12 and < 18 .

The most recent data described in this report are from the 2001 study period which includes the months of October-December 2000 for the in-center hemodialysis patients and October 2000-March 2001 for the peritoneal dialysis patients. This report also compares the 2001 study period findings to findings from previous study periods AND it identifies opportunities to improve care for dialysis patients.

The full report can be found on the Internet at www.hcfa.gov/quality/3m.htm. Power Point files containing all of the figures in this report can also be found at this Internet site. Please feel free to use any of these slides in presentations and quality improvement activities.

This report contains four major sections: **Background and Project Methods**, **Adult In-Center Hemodialysis Patients**, **Adult Peritoneal Dialysis Patients**, and **new this year, Pediatric In-Center Hemodialysis Patients** (aged ≥ 12 and < 18). Also, the lists of tables and figures have been moved to the back of the report as Section VII.

This report also contains some new features or tools to assist dialysis providers in using the information from this project. Appendices 9 and 10 (pages 103 and 105) contain tear out CPM Outcomes Comparison Tools (one for hemodialysis and one for peritoneal dialysis) that providers can use to record their facility-specific results for comparisons to national and network findings (network rates are only available for hemodialysis). (Note: Each provider will have to calculate its own facility-specific results to record on this tool.) Even though the national and network hemodialysis findings included in this report are from the time period October – December 2000, your facility's data that you calculate and enter on this form can be from any time period (national peritoneal dialysis findings are from the time period October 2000 – March 2001). Appendix 8 provides you with over 25 network level hemodialysis findings that you can use to record on your Outcomes Comparison Tool (Appendix 9). On the back of each tool are two graphs that can be used to record monthly facility-specific adequacy and anemia management results. We encourage each dialysis facility to use these tools. Consider posting the charts somewhere in the dialysis

facility that is visible to staff and patients so everyone can follow the monthly entries.

The **Background and Project Methods** section beginning on page 13, provides information on the Medicare ESRD program and why the ESRD CPM Project was initiated. Patient selection criteria and data collection and analysis methodology are also described. A short summary of each CPM collected for this project is included, with Appendix 1 providing a more detailed description of each CPM.

The **Adult In-Center Hemodialysis Patients**, **Adult Peritoneal Dialysis Patients** and the **Pediatric In-Center Hemodialysis Patients** sections describe the findings for each patient sample for the 2001 study period and compare these findings to previous study periods.

This report provides the dialysis community with an initial look at network and national profiles for the clinical measures that were collected for the ESRD CPM Project. Additional Supplemental Reports, describing other analyses of the data, will be prepared during 2002.

While significant improvements in care have occurred, the opportunities to improve care for dialysis patients in the U.S. in the area of adequacy of dialysis, vascular access, and anemia management continue. Every dialysis caregiver should be familiar with the clinical practice guidelines developed by the Renal Physicians Association (1) and the National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF-DOQI) (2, 3, 4, 5). Your Network staff and Medical Review Board are also available to assist you in identifying and developing improvement efforts.

In the future, the ESRD Networks, in collaboration with dialysis facilities, will continue to assess the ESRD CPMs for dialysis patients in the U.S. The purpose of this effort will be to assess improvement in care and to encourage further improvements. The ultimate goal is to improve care for all ESRD patients.

ESRD CPM DATA TRENDS

The Figures on the following pages show the trends in the ESRD CPM data for various study periods.

Please note that when only a "year" such as 1999 is used, it refers to the last three months in that "year" for the hemodialysis patients and for the peritoneal dialysis patients, the "year" refers to the first three months of the current year and the last three months of the prior year. Also, "adult" refers to ages ≥ 18 years and "pediatric" refers to ages ≥ 12 and < 18 years.

NOTE: Highlights of important findings from the 2001 ESRD CPM Project may be found on the following pages:

Adult in-center hemodialysis patients, page 10
Adult peritoneal dialysis patients, page 11
Pediatric in-center hemodialysis patients, page 12

Hemodialysis Adequacy Trends

Figure 2: Percent of adult in-center hemodialysis patients with mean $Kt/V \geq 1.2$ in October-December 2000, compared to previous study periods. 2001 ESRD CPM Project.

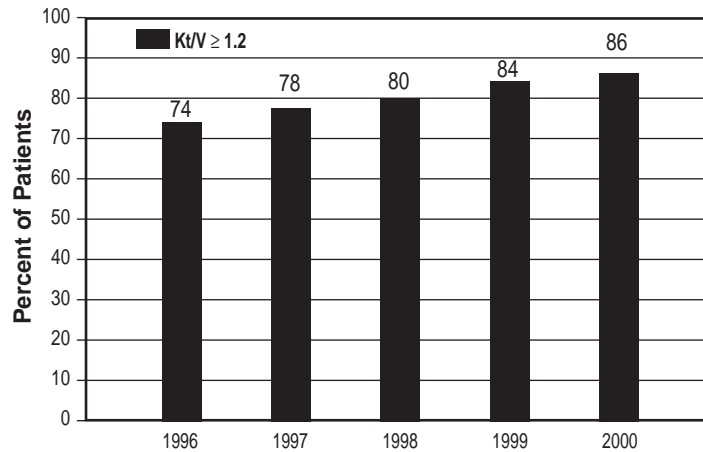
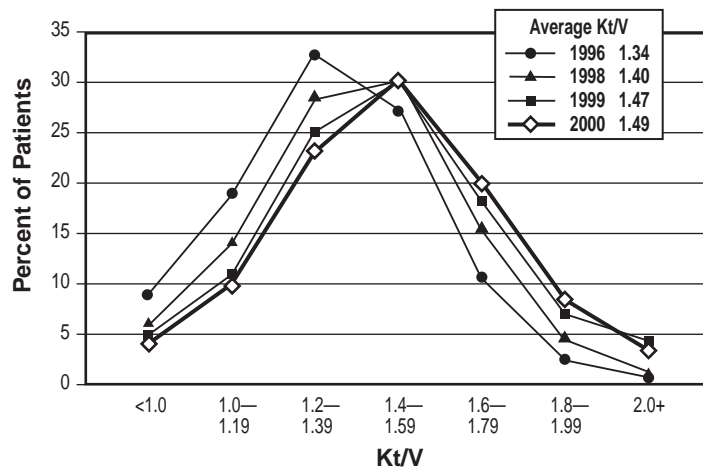
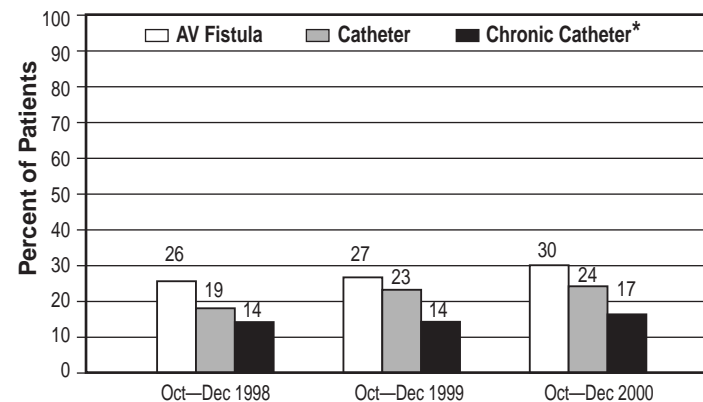


Figure 3: Distribution of mean calculated Kt/V values for adult in-center hemodialysis patients October-December 2000 compared to previous study periods. 2001 ESRD CPM Project.



Vascular Access Trends

Figure 4: Vascular access type for all adult in-center hemodialysis patients on their last hemodialysis session during the study period. 2001 ESRD CPM Project.



* Chronic catheter defined as use of a catheter access continuously for 90 days or longer.

Peritoneal Dialysis Adequacy Trends

Figure 5: Distribution of mean weekly Kt/V_{urea} values for adult CAPD patients, October 2000-March 2001 compared to previous study periods. 2001 ESRD CPM Project.

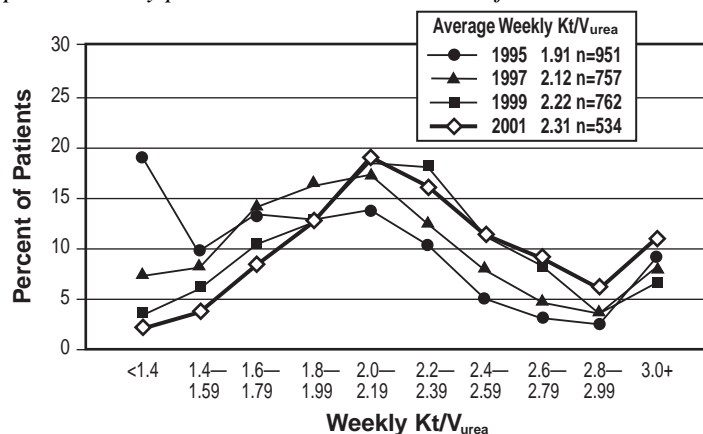


Figure 6: Distribution of mean weekly creatinine clearance values ($L/week/1.73m^2$) for adult CAPD patients, October 2000-March 2001 compared to previous study periods. 2001 ESRD CPM Project.

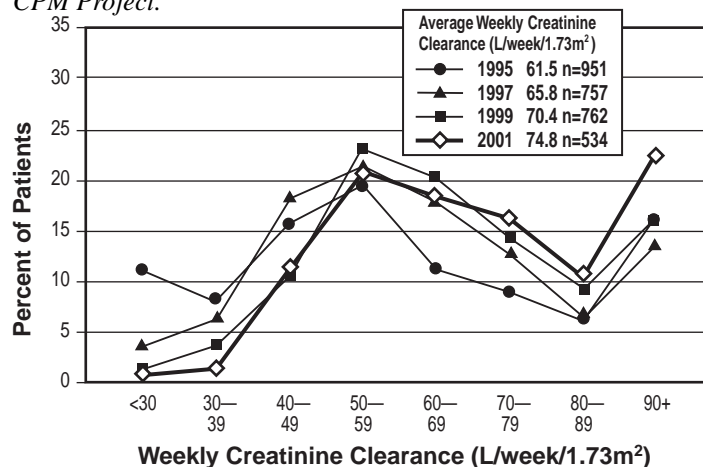
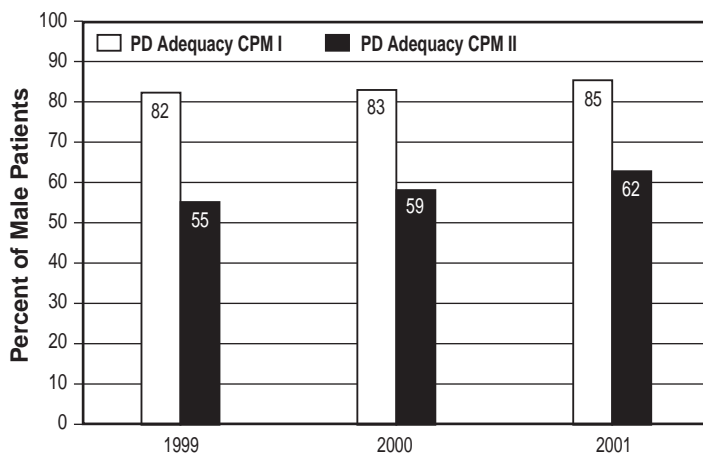


Figure 7: Percent of adult peritoneal dialysis patients with total solute clearance for urea and creatinine measured at least once during the study period (PD Adequacy CPM I) and with total solute clearance calculated in a standard way* (PD Adequacy CPM II) October 2000-March 2001 compared to previous study periods. 2001 ESRD CPM Project.



* See Appendix 1 for a complete description of the standard methods to calculate solute clearance for urea and creatinine.

Anemia Management Trends

Figure 8: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, October-December 2000 compared to previous study periods. 2001 ESRD CPM Project.

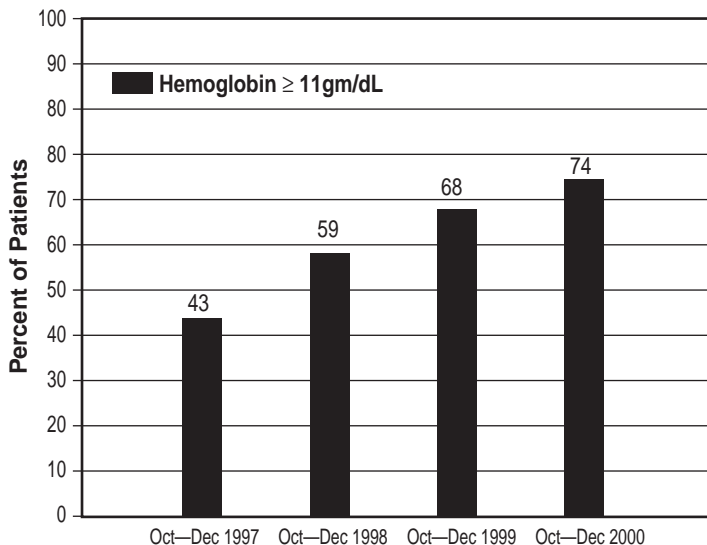


Figure 10: Percent of adult peritoneal dialysis patients with mean hemoglobin ≥ 11 gm/dL, October 2000-March 2001 compared to previous study periods. 2001 ESRD CPM Project.

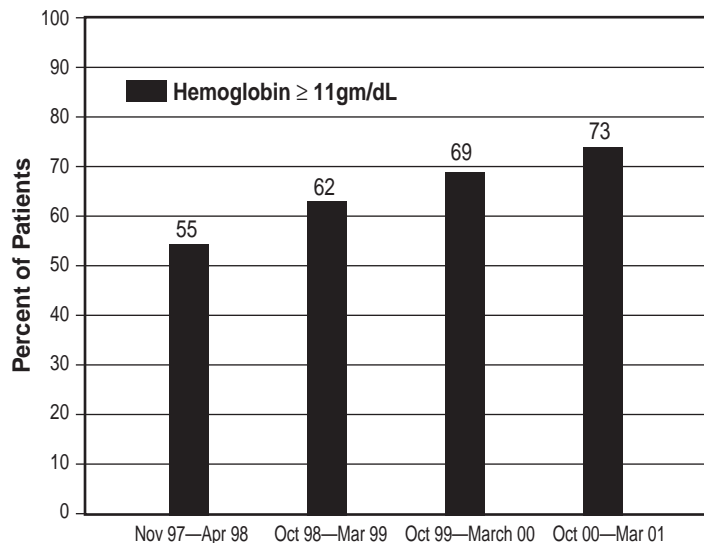


Figure 9: Distribution of mean hemoglobin values for adult in-center hemodialysis patients, October-December 2000 compared to previous study periods. 2001 ESRD CPM Project.

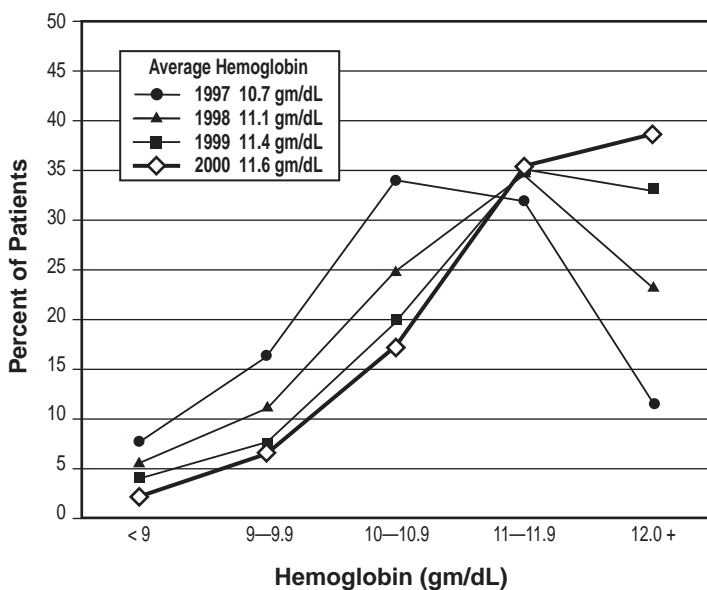
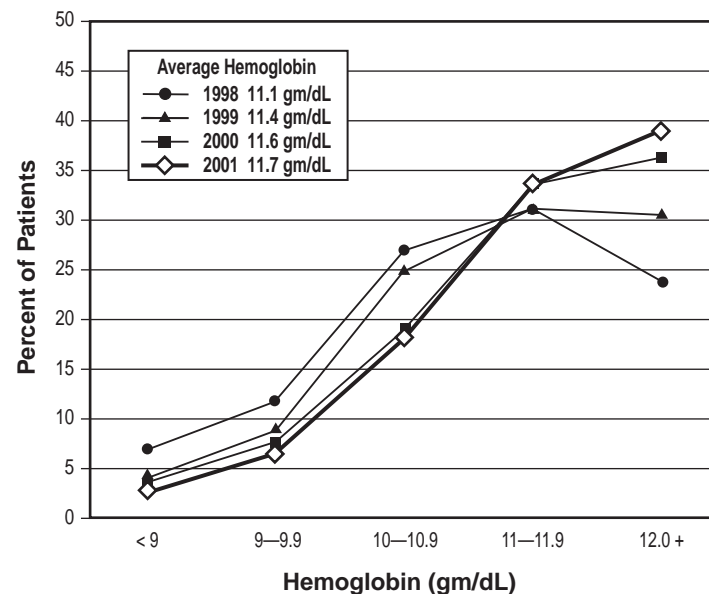


Figure 11: Distribution of mean hemoglobin values for adult peritoneal dialysis patients October 2000-March 2001 compared to previous study periods. 2001 ESRD CPM Project.



Pediatric Dialysis Trends

Figure 12: Distribution of mean delivered calculated Kt/V values for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients. 2001 ESRD CPM Project.

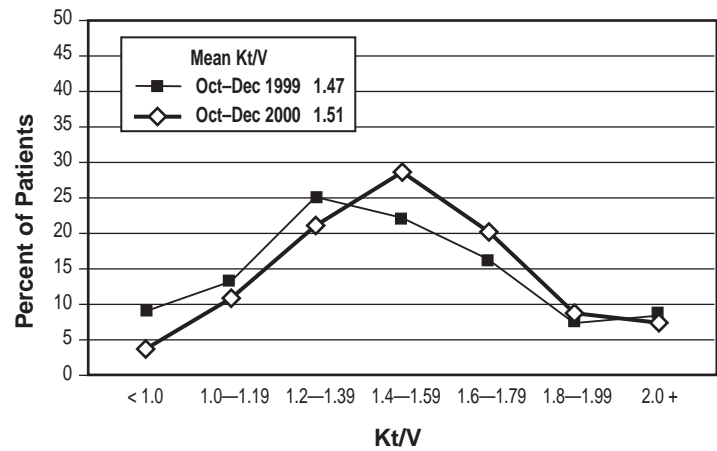


Figure 13: Vascular access type for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients. 2001 ESRD CPM Project.

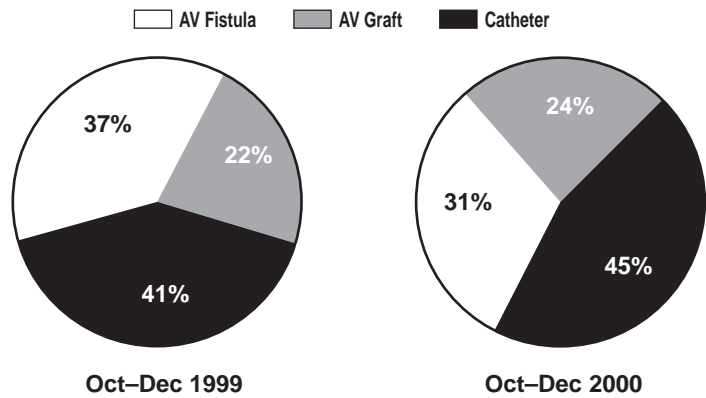
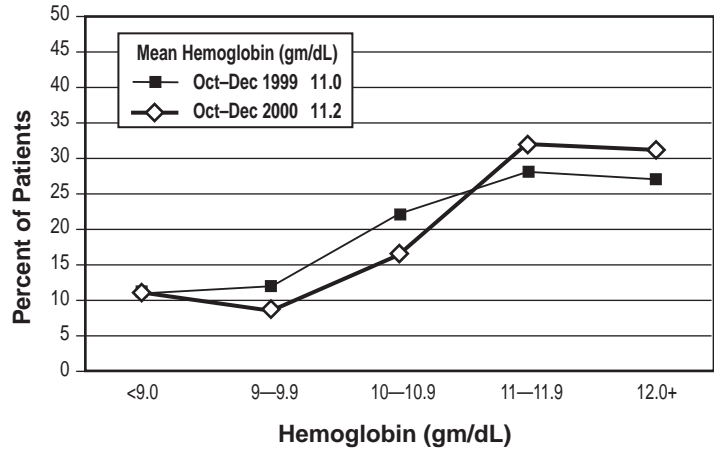


Figure 14: Distribution of mean hemoglobin values for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients. 2001 ESRD CPM Project.



HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2001 ESRD CPM DATA

Adult In-Center Hemodialysis Patients

The data are from October-December 2000:

Hemodialysis Adequacy

- 80% of patients had monthly adequacy measurements performed (HD Adequacy CPM I)
- 52% of patients had their delivered Kt/V calculated using either UKM or the Daugirdas II formula (HD Adequacy CPM II)
- 91% of patients on dialysis for 6 months or more and dialyzing three times a week had a mean delivered adequacy dose of Kt/V ≥ 1.2 (HD Adequacy CPM III)
- 86% of prevalent patients had a mean delivered adequacy dose of Kt/V ≥ 1.2 (FIGURE 2)
- Median Kt/V was 1.49
- 82% of patients had a mean URR $\geq 65\%$
- Median URR was 71.4%
- Median dialysis session length was 210 minutes

Vascular Access

- 27% of incident patients were dialyzed using an AV fistula (AVF) (Vascular Access CPM I)
- 30% of prevalent patients were dialyzed using an AVF (Vascular Access CPM I) (FIGURE 4)
- 17% of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer (Vascular Access CPM II)
- 47% of prevalent patients with an AV graft were routinely monitored for the presence of stenosis (Vascular Access CPM III)

Anemia Management

- 38% of targeted patients prescribed Epoetin had a hemoglobin between 11.0-12.0 gm/dL (Anemia Management CPM I)
- 91% of patients who met the inclusion criteria¹ had at least one measured transferrin saturation value and one serum ferritin concentration value (Anemia Management CPM IIa)
- 71% of patients who met the inclusion criteria¹ had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration ≥ 100 ng/mL (Anemia Management CPM IIb)
- 73% of patients who met the inclusion criteria¹ were prescribed intravenous iron in at least one month during the study period (Anemia Management CPM III)
- 74% of patients had a mean hemoglobin ≥ 11 gm/dL (FIGURE 8)
- 9% of patients had a mean hemoglobin < 10.0 gm/dL
- Median hemoglobin was 11.7 gm/dL
- Median IV Epoetin dose was 63.3 units/kg
- Median SC Epoetin dose was 54.8 units/kg

Serum Albumin

- 29% of patients had a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)²
- 80% of patients had a mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP)
- Median serum albumin BCG/BCP was 3.8/3.6 gm/dL

¹See Appendix 1 for a description of the inclusion criteria.

² BCG = bromcresol green, BCP = bromcresol purple; these are two different laboratory methods for assaying serum albumin.

HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2001 ESRD CPM DATA

Adult Peritoneal Dialysis Patients

The data are from October 2000-March 2001:

Peritoneal Dialysis Adequacy

- 85% of patients had a least one measured total solute clearance for urea and creatinine (PD Adequacy CPM I) during the six month study period (FIGURE 7)
- 62% of patients had their total solute clearance for urea and creatinine calculated in a standard way¹ (PD Adequacy CPM II) (FIGURE 7)
- 69% of CAPD patients had a mean weekly Kt/V_{urea} of ≥ 2.0 and a mean weekly creatinine clearance $\geq 60\text{L/week}/1.73\text{m}^2$ OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.(PD Adequacy CPM III) (FIGURE 52)
- 62% of Cycler patients with a daytime dwell had a mean weekly Kt/V_{urea} of ≥ 2.1 and a mean weekly creatinine clearance $\geq 63\text{ L/week}/1.73\text{m}^2$ OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.(PD Adequacy CPM III) (FIGURE 52)
- 64% of Cycler patients without a daytime dwell had a mean Kt/V_{urea} of ≥ 2.2 and a mean weekly creatinine clearance $\geq 66\text{ L/week}/1.73\text{m}^2$ OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.(PD Adequacy CPM III) (FIGURE 52)
- Median weekly Kt/V_{urea} for CAPD patients was 2.23
- Median weekly Kt/V_{urea} for Cycler patients with a daytime dwell was 2.24
- Median weekly Kt/V_{urea} for Cycler patients without a daytime dwell was 2.22

Anemia Management

- 39% of targeted patients prescribed Epoetin had a mean hemoglobin between 11.0-12.0 gm/dL (Anemia Management CPM I)
- 72% of patients who met the inclusion criteria² had at least two measured transferrin saturation values and two serum ferritin concentration values during the six month study period (Anemia Management CPM IIa)
- 75% of patients who met the inclusion criteria² had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration $\geq 100\text{ ng/mL}$ (Anemia Management CPM IIb)
- 23% of patients who met the inclusion criteria² were prescribed intravenous iron in at least one of the two-month periods during the study period (Anemia Management CPM III)
- 73% of patients had a mean hemoglobin $\geq 11\text{ gm/dL}$ (FIGURE 10)
- Median hemoglobin was 11.7 gm/dL
- Median SC Epoetin dose was 38.8 units/kg
- Median IV Epoetin dose was 62.0 units/kg

Serum Albumin

- 14% of patients had a mean serum albumin $\geq 4.0/3.7\text{ gm/dL}$ (BCG/BCP)³
- 56% of patients had a mean serum albumin $\geq 3.5/3.2\text{ gm/dL}$ (BCG/BCP)
- Median serum albumin BCG/BCP was 3.6/3.3 gm/dL

¹ See Appendix 1 for a description of standard ways for calculating total solute clearance.

² See Appendix 1 for a description of the inclusion criteria.

³ BCG = bromcresol green, BCP = bromcresol purple; these are two different laboratory methods for assaying serum albumin.

HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2001 ESRD CPM DATA

Pediatric In-Center Hemodialysis Patients (age ≥ 12 and < 18)¹

The data are from October-December 2000:

Hemodialysis Adequacy

- 85% of patients had a mean delivered adequacy dose of $Kt/V \geq 1.2$
- Median Kt/V was 1.48
- Median dialysis session length was 210 minutes

Vascular Access

- 31% of prevalent patients were dialyzed using an AV fistula (AVF) (FIGURE 13)
- 31% of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer
- 41% of prevalent patients with an AVF or an AV graft were routinely monitored for the presence of stenosis

Anemia Management

- 63% of patients had a mean hemoglobin ≥ 11 gm/dL
- Median hemoglobin was 11.4 gm/dL
- Median IV Epoetin dose was 75.2 units/kg

Serum Albumin

- 43% of patients had a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)²
- 84% of patients had a mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP)
- Median serum albumin BCG/BCP was 3.9/3.6 gm/dL

¹ The ESRD Clinical Performance Measures (CPMs) do not apply to patients < 18 years of age.

² BCG = bromocresol green, BCP = bromocresol purple; these are two different laboratory methods for assaying serum albumin.

IMPORTANT NOTE

The data in this report are intended to stimulate the development of quality improvement (QI) projects in dialysis facilities. The data collected for this project were necessarily limited: not all dialytic parameters that influence patient care for these clinical measures were collected. In addition, the project did not attempt to develop facility-specific profiles of care.

During 2002, we plan to provide a series of supplemental reports. In these reports we will provide more detailed analysis using data collected for the ESRD CPM Project as well as other data from which we can derive information about the patients in the sample identified for this project.

As you review this report, ask yourself questions about how your patients' clinical characteristics compare to these national hemodialysis and peritoneal dialysis patient profiles and Network hemodialysis patient profiles. Additional information must be collected at your facility if you wish to answer these questions and develop ways to improve patient care for your patients. Your ESRD Network staff and Medical Review Board members are available to assist you in using these data in your QI activities and in developing facility-specific QI projects.

II. BACKGROUND AND PROJECT METHODS

A. MEDICARE'S ESRD PROGRAM

The Social Security Amendments of 1972 (PL 92-603) extended Medicare coverage to individuals with end-stage renal disease (ESRD) or chronic kidney failure who require dialysis or a kidney transplant to maintain life. To qualify for Medicare under the renal provision, a person must have ESRD and either be entitled to a monthly insurance benefit under Title II of the Social Security Act (or an annuity under the Railroad Retirement Act); or be fully or currently insured under Social Security; or be the spouse or dependent child of a person who meets at least one of these last two requirements. There is no minimum age for eligibility under the renal disease provision. The incidence of treated ESRD in the United States is 315 per million population (6). As of December 31, 2000, there were 273,333 patients receiving dialysis therapy in the United States (7).

ESRD Health Care Quality Improvement Program (HCQIP)

The Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), which oversees the Medicare program, contracts with 18 ESRD Network Organizations throughout the United States. The ESRD Networks perform oversight activities to assure the appropriateness of services and protection for ESRD patients. In 1994, CMS, with input from the renal community, reshaped the approach of the ESRD Network program to quality assurance and improvement in order to respond to the need to improve the care of Medicare ESRD patients (8). This approach has been named the ESRD Health Care Quality Improvement Program (HCQIP).

The ESRD HCQIP gives the ESRD Networks and CMS a chance to demonstrate that health care provided to renal Medicare beneficiaries can be measurably improved. The HCQIP is based on the assumption that most health care providers need and welcome both information and, where necessary, help in applying the tools and techniques of quality management (9).

ESRD Core Indicators Project

One activity included in the ESRD HCQIP was the National/Network ESRD Core Indicators Project (CIP). This project was initiated as a national intervention approach to assist dialysis providers in the improvement of patient care and outcomes. The ESRD CIP was CMS's first nationwide population-based study designed to assess and identify opportunities to improve the care of patients with ESRD (10). This project established the first consistent clinical ESRD database. The elements included in the database represent clinical measures thought to be indicative of key components of care surrounding dialysis. As such, the data points are considered "indicators" for use in triggering improvement activities. The ESRD CIP was initiated in 1994, and in 1999 this project was merged with the ESRD Clinical Performance Measures Project.

ESRD Clinical Performance Measures Project

Section 4558(b) of the Balanced Budget Act (BBA) of 1997 required CMS to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. To implement this legislation, CMS funded the development of Clinical Performance Measures (CPMs) based on the National Kidney Foundation (NKF) Dialysis Outcomes Quality Initiative (DOQI) Clinical Practice Guidelines (2, 3, 4, 5).

For information regarding the development of the CPMs, refer to the 1999 Annual Report, End-Stage Renal Disease Clinical Performance Measures Project on the Internet at www.hcfa.gov/quality/3m.htm.

On March 1, 1999, the ESRD Core Indicators Project was merged with the ESRD CPM Project and this project is now known as the ESRD CPM Project. The ESRD CPMs are similar to the core indicators with the addition of measures for assessing vascular access.

This 2001 ESRD CPM Project Annual Report provides the results of some of the CPMs on a sample of adult in-center hemodialysis patients, adult peritoneal dialysis patients, and on all pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients; it does not provide results on a dialysis facility-specific basis. The quality of dialysis services is reported for adult and pediatric in-center hemodialysis patients for the last quarter in 2000 and adult peritoneal dialysis patients for the time period October 2000–March 2001.

CMS and the ESRD Networks are committed to improving ESRD patient care and outcomes by providing tools that can be used by the renal community in assessing patient care processes and outcomes and identifying opportunities for improvement. One of these tools includes data feedback reports based on the clinical information obtained from the ESRD CPM Project, formerly known as the ESRD CIP. We invite the renal community to provide us with ideas and feedback as to ways CMS and the Networks can best help the community to improve patient care.

B. PROJECT METHODS

The purpose of the ESRD CPM Project is to provide comparative data to ESRD caregivers to assist them in assessing and improving the care provided to dialysis patients. The data collected in 1994 (for the time period October–December 1993) established a baseline estimate for important clinical measures of care for adult in-center hemodialysis patients in the United States (11). From 1994 to 1998, CMS collected ESRD data under the ESRD CIP. The purpose of these data collections was to determine whether patterns in these clinical measures had changed and if opportunities to improve care continued to exist (12–16).

The first data collection effort for the ESRD CPMs was conducted in 1999. It examined data from October–December 1998 for adult in-center hemodialysis patients, and from October 1998 to March 1999 for adult peritoneal dialysis patients. Information

to calculate the CPMs was collected and further opportunities to improve care were identified (17).

The second data collection effort for the ESRD CPMs, conducted in 2000, examined data from October-December 1999 for adult and pediatric in-center hemodialysis patients, and from October 1999-March 2000 for adult peritoneal dialysis patients (18).

This report describes the findings from the third data collection effort for the ESRD CPMs which was conducted in 2001 and collected data from October-December 2000 for adult and pediatric in-center hemodialysis patients, and from October 2000-March 2001 for adult peritoneal dialysis patients. These data help to determine if there are opportunities to improve care and to evaluate patterns of care across the nation.

The Sample

Annually, each ESRD Network conducts a survey of ESRD facilities to validate the census of ESRD patients in the Network at the end of the calendar year. In March 2001, a listing of adult (aged ≥ 18 years as of September 30, 2000) in-center hemodialysis and adult peritoneal dialysis patients who were alive and dialyzing on December 31, 2000, was obtained from each of the 18 ESRD Networks. The listing included, but was not limited to, the following information about each patient who met the project criteria: last name, first name, middle initial, date of birth, gender, race, Social Security and/or Health Insurance Claim number, underlying etiology of ESRD, date that dialysis was initiated, and provider number of the facility where the patient was dialyzing.

From this universe of patients, a national random sample, stratified by Network, of adult in-center hemodialysis patients was drawn. The sample size of adult in-center hemodialysis patients was selected to allow estimation of a proportion with a 95% confidence interval around that estimate no larger than 10 percentage points (i.e., $\pm 5\%$) for Network-specific estimates of the key Hemodialysis CPMs and other indicators. Additionally a 30% over-sample was drawn to compensate for an anticipated non-response rate and to assure a large enough sample of the adult in-center hemodialysis patient population who were dialyzing at least six months prior to October 1, 2000. The final sample consisted of 8,853 in-center hemodialysis patients.

The peritoneal dialysis patient sample included a random selection of 5% of adult peritoneal dialysis patients in the nation. Additionally, a 10% over-sample was drawn to compensate for an anticipated non-response rate. The final sample consisted of 1,439 peritoneal dialysis patients.

All pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients in the U.S. ($n = 516$) were included in the 2001 ESRD CPM Study.

A 5% national random sample of hemodialysis facilities was also drawn and consisted of 214 hemodialysis facilities. These facilities were surveyed to obtain information regarding post-dialysis BUN sampling, dialyzer reuse, and measurement of total cell volume of reprocessed dialyzers.

This year's data collection was unique in that it included a 5% sample of adult Asian in-center hemodialysis patients in the U.S. A Supplemental Report describing the results of the data collected on the Asian adult in-center hemodialysis patients is planned for 2002.

Data Collection

Three data collection forms were used: a three-page in-center hemodialysis form, a four-page peritoneal dialysis form, and a one-page hemodialysis facility-specific form (Appendices 2, 3, and 4 respectively); the use of these forms was authorized through the National Institutes of Health (NIH) clinical exemption process. Descriptive information on each selected patient and hemodialysis facility was printed onto gummed labels, and sent to the individual ESRD Networks along with the forms to be used to collect the data. If demographic information (e.g., name, date of birth, race) or clinical information (e.g., date that initial dialysis occurred) was incorrect, facility staff were asked to correct the information on the forms. Staff at ESRD facilities were also asked to abstract ethnicity and clinical information from the medical record of each selected patient.

In May 2001, the data collection forms for patients and facilities in the sample were distributed to ESRD facilities. Clinical information contained in the medical record was abstracted for each patient in the adult hemodialysis sample and among all pediatric in-center hemodialysis patients who received in-center hemodialysis at any time during October, November, and December 2000. Clinical information contained in the medical record was also abstracted for each patient in the adult peritoneal dialysis sample who was receiving peritoneal dialysis at any time during the two-month periods of October–November 2000, December 2000–January 2001, and February–March 2001.

Completed forms were returned to the appropriate Network, where data were reviewed for acceptability and manually entered into a Visual FoxPro data entry program. In August 2001, each Network sent a copy of their Visual FoxPro data files to CMS's contractor, ESRD Network 9/10, in Indianapolis, Indiana, where the data were aggregated and then submitted to CMS, in an Epi Info, v.6.04a file (19), for the initial analysis.

Note Regarding Race:

In this report several tables describe important clinical characteristics of adult in-center hemodialysis and peritoneal dialysis patients for the following race groups: American Indian/Alaska Native, Asian/Pacific Islander, Black, White, and Other/Unknown. In the figures, these clinical characteristics are compared by race group; however, the comparisons are limited to White vs. Black. The reason for this is sample size. Because of small sample size (Table 2), the 95% confidence intervals for estimates for American Indian/Alaska Native, Asian/Pacific Islander, etc. race groups are very broad. On the other hand, the sample size for White and Black patients was large enough to provide stable estimates; i.e., the 95% confidence intervals are narrow.

C. CLINICAL PERFORMANCE MEASURES (CPMs)

The clinical information abstracted by facility staff is used in this report to describe some of the CPMs that were developed from the NKF-DOQI Guidelines and other quality indicators for several conditions of care for adult dialysis patients. These CPMs do not apply to patients under the age of 18 years. The CPMs were developed in the areas of hemodialysis and peritoneal dialysis adequacy, vascular access and anemia management. A complete description of the 15 CPMs appears in Appendix 1. The CPMs used for this report were modified slightly from the initial version for clarification and to facilitate data analysis.

The Hemodialysis Adequacy CPMs described in this report are:

- I. The patient's delivered dose of hemodialysis is measured at least once per month.
- II. The patient's delivered dose of hemodialysis reported in the patient's chart is calculated by using formal urea kinetic modeling (UKM) or the Daugirdas II formula for Kt/V .
- III. The patient's (for those patients on hemodialysis six months or longer and dialyzing three times per week) delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month study period) of hemodialysis is $Kt/V \geq 1.2$.

The clinical information collected to calculate these adequacy CPMs also allows us to describe other aspects of dialysis adequacy (or indicators), such as the mean Kt/V values for hemodialysis patients in each Network area and in the US.

The Peritoneal Dialysis Adequacy CPMs described in this report are:

- I. The patient's total solute clearance for urea and creatinine is measured routinely (defined for this report as at least once during the six-month study period).
- II. The patient's total solute clearance for urea (weekly Kt/V_{urea}) and creatinine (weekly creatinine clearance) is calculated in a standard way. (See Peritoneal Dialysis Adequacy CPM II in Appendix 1.)
- III. For patients on continuous ambulatory peritoneal dialysis (CAPD), the delivered peritoneal dialysis dose is a total Kt/V_{urea} of at least 2.0 per week and a total creatinine clearance (CrCl) of at least 60 L/week/1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

For CCPD patients (cycler patients with a daytime dwell), the weekly delivered peritoneal dialysis dose is a

total Kt/V_{urea} of at least 2.1 and a weekly total creatinine clearance of at least 63 L /1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

For NIPD patients (cycler patients without a daytime dwell), the weekly delivered peritoneal dialysis dose is a total Kt/V_{urea} of at least 2.2 and a weekly total creatinine clearance of at least 66 L /1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

The Vascular Access CPMs described in this report are:

- I. A primary arterial venous fistula (AVF) should be the access for at least 50% of all new patients initiating hemodialysis. A native AVF should be the primary access for 40% of prevalent patients undergoing hemodialysis.
- II. Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters (continuously for ≥ 90 days) as their permanent chronic dialysis access.
- III. A patient's AV graft should be routinely monitored for stenosis. (See Vascular Access CPM III in Appendix 1 for a list of techniques and frequency of monitoring used to screen for the presence of stenosis.)

The Anemia Management CPMs described in this report are:

- I. The target hemoglobin for patients prescribed Epoetin is 11-12 gm/dL. Patients with a mean hemoglobin >12 gm/dL and not prescribed Epoetin were excluded from analysis for this CPM.
- IIa. For anemic patients (hemoglobin < 11 gm/dL in at least one study month) or patients prescribed Epoetin, the percent transferrin saturation and serum ferritin concentration are assessed (measured) at least once in a three-month period.
- IIb. For all anemic patients (hemoglobin < 11 gm/dL in at least one study month) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation $\geq 20\%$ were documented during the three-month study period.
- III. All anemic patients (hemoglobin < 11 gm/dL in at least one study month) or patients prescribed Epoetin, and with at least one transferrin saturation $< 20\%$ or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was $\geq 50\%$ or the mean serum ferritin concentration was ≥ 800 ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

The clinical information collected to calculate these CPMs allows us to describe other aspects of anemia management (or indicators). For example, the percents of patients with a mean hemoglobin ≥ 11 gm/dL, 11-12.9 gm/dL and < 10 gm/dL are profiled in this report. Additionally, the percents of all patients with mean transferrin saturation $\geq 20\%$, mean serum ferritin concentration ≥ 100 ng/mL, and the percents of patients prescribed subcutaneous (SC) Epoetin or intravenous (IV) iron are profiled.

All monthly recorded data were used in determining the percent of patients prescribed Epoetin. A "held" dose of Epoetin was entered as "zero" units, and was included in the calculation of the weekly Epoetin dose. The average prescribed Epoetin dose (units/kg) was stratified by hemoglobin levels.

D. SERUM ALBUMIN

Although serum albumin is not a CPM for this data collection period, it is one of the original core indicators and was chosen as an indicator for assessing mortality risk for adult in-center hemodialysis patients and adult peritoneal dialysis patients. This project collects the serum albumin value as well as the test method (bromocresol green [BCG] method and bromocresol purple [BCP] method) because these two methods are commonly used for determining serum albumin concentrations and have been reported to yield systematically different results—the BCG method yielding higher serum albumin concentrations than the BCP method (20).

For the history of this project, mean serum albumin values < 3.5 gm/dL by the BCG method have been defined as an indicator of inadequate serum albumin. Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was nearly the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we have historically also defined a BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. Mean serum albumin values ≥ 4.0 gm/dL (BCG method) and ≥ 3.7 gm/dL (BCP method) have been defined as indicators of optimal serum albumin.

In June 2000, the NKF K/DOQI Guidelines for Nutrition in Chronic Renal Failure were published. Guideline 3 of the Clinical Practice Guidelines states that a pre-dialysis or stabilized serum albumin equal to or greater than the lower limit of normal range (approximately 4.0 gm/dL for the bromocresol green method) is the outcome goal (21).

Findings from this project allow us to report the percent of patients with mean serum albumin values ≥ 4.0 gm/dL (BCG method) and ≥ 3.7 gm/dL (BCP method) and the percent of patients with mean serum albumin values ≥ 3.5 gm/dL (BCG method) and ≥ 3.2 gm/dL (BCP method) for adult hemodialysis patients in each Network area and nationally, and nationally for adult peritoneal dialysis patients and pediatric hemodialysis patients.

E. PEDIATRIC IN-CENTER HEMODIALYSIS PATIENTS

Although there are no CPMs established for the pediatric age group, demographic and clinical information from October-December 2000 were collected on all adolescent patients (≥ 12 and < 18 years) in the U.S. in order to describe several core indicators of dialysis care. These core indicators included hemodialysis adequacy, vascular access, anemia management, and serum albumin.

F. DATA ANALYSIS

Adult In-Center Hemodialysis

Initial analysis for the CPMs and other indicators focused on the following elements: paired pre- and post-dialysis BUN values with patient height and weight and dialysis session length (used to calculate Kt/V values); hemoglobin values; vascular access information; and serum albumin.

Inclusion of a case in the analysis required that data be available for at least one of the months in the three-month project period, with at least one paired pre- and post-dialysis BUN, at least one hemoglobin, and at least one serum albumin. We were able to include for analysis 8,416 of the 8,853 patients from the sample (response rate = 95%) (TABLE 1).

Characteristics regarding the gender, race, ethnicity, age, diagnosis, and duration of dialysis (years) of ESRD for these patients are shown in Table 2. As expected, the characteristics of this random sample were very similar to the characteristics of the overall US hemodialysis population (6). Data regarding Epoetin use, serum ferritin concentrations, transferrin saturation levels, iron use, KUF (a measure of fluid removal), and actual time on dialysis were also analyzed. The initial analysis utilized Epi Info and Statistical Package for the Social Sciences (SPSS) software (19, 22).

For this report, each patient's mean value for the three-month project period was determined from the available data for the following items: Kt/V, dialysis session length, dialyzer KUF, blood pump flow rates, hemoglobin, transferrin saturation, serum ferritin concentration, prescribed Epoetin dose and route of administration, and serum albumin. Information on prescription and route of administration of iron was collected. Because we had data from a stratified random sample of patients (i.e., a separate random sample from each of the 18 Networks), it was necessary to weight the collected data in order to obtain unbiased estimates of mean clinical values for the total population. This weighting was done according to the proportion of each Network's total population sampled. Aggregate national results shown in this report were derived from weighted data; Network-specific comparisons were derived from unweighted data.

TABLE 1: Number of adult in-center hemodialysis patients in each Network in December 2000, sample size and response rate for the 2001 ESRD CPM Project.

Network	# HD Patients Dec 2000	Sample Size	# Acceptable Forms [^]	Response Rate %
1	8,705	486	448	92.2
2	18,819	497	448	90.1
3	10,880	491	471	95.9
4	11,905	491	443	90.2
5	14,531	494	475	96.2
6	22,357	499	478	95.8
7	14,116	494	474	96.0
8	14,077	494	477	96.6
9	16,881	496	473	95.4
10	10,276	488	449	92.0
11	14,667	494	476	96.4
12	8,745	487	452	92.8
13	10,634	490	478	97.6
14	20,324	498	481	96.6
15	10,289	488	472	96.7
16	5,697	476	466	97.9
17	12,144	491	469	95.5
18	18,088	499	486	97.4
Total	243,135	8,853	8,416	95.1

[^] A form was considered acceptable if the patient met the selection criteria for inclusion in the study and if data were provided for at least one of the months in the fourth quarter of 2000 for the following items: 1) hemoglobin; 2) paired pre- and post-dialysis BUN values; and 3) serum albumin value.

Two or more monthly values for these clinical measures were available for 97% of patients for hemoglobin and 96% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 91% of patients. At least one monthly paired pre- and post-dialysis BUN value was available for 100% of patients, and two or more were available for 95%. Monthly paired pre- and post-dialysis BUN values were available for 81% of patients.

TABLE 2: Characteristics of adult in-center hemodialysis patients in the 2001 ESRD CPM Project compared to those of all in-center hemodialysis patients in the US in 1999.

Patient Characteristic	2001 CPM Sample for Analysis		All US in 1999*	
	# [^]	%	# in 1000s	%
TOTAL	8416	100	212.1	100
GENDER				
Men	4376	52	111.9	53
Women	4032	48	100.0	47
RACE				
American Indian/ Alaska Native	144	2	3.7	2
Asian/Pacific Islander	328	4	7.5	4
Black	3103	37	83.7	39
White	4403	52	113.2	53
Other/Unknown	438	5	4.0	2
ETHNICITY				
Hispanic	1086	13	24.2	11
Non-Hispanic	6926	82	187.9	89
Other/Unknown	404	5	0	0
AGE GROUP (years)				
18-49	1990	24	48.9**	23
50-59	1655	20	39.6	19
60-64	927	11	23.4	11
65-69	1031	12	26.6	13
70-79	1976	24	51.7	24
80+	837	10	20.8	10
DIAGNOSIS				
Diabetes mellitus	3496	42	86.0	41
Hypertension	2147	26	59.5	28
Glomerulonephritis	971	12	24.4	12
Other/Unknown	1802	21	42.2	20
DURATION of DIALYSIS (years)				
<0.5	997	12		
0.5-0.9	1152	14		
1.0-1.9	1719	20		
2.0+	4441	53		

*USRDS: 2001 Annual Data Report, Bethesda, MD, National Institutes of Health, 2001. Tables D.4 and D.5.

[^] Subgroup totals may not equal 8,416 due to missing data.

** For ages 20-49 years

Note: Percentages may not add up to 100% due to rounding.

Adult Peritoneal Dialysis

The initial analysis focused on the adequacy of peritoneal dialysis CPMs, anemia management CPMs, and serum albumin values. Inclusion of a case for analysis required that the patient received peritoneal dialysis at least one month during the time period October 2000–March 2001. Of the 1,439 patients sampled, 1,342 patients were included in the sample for analysis (93% response rate) (TABLE 3). Selected patient characteristics of this sample for analysis are shown in Table 4.

For this report, each patient's mean value for the six-month study period was determined from available data for the following items: weekly Kt/V_{urea} , weekly creatinine clearance, hemoglobin, serum albumin, prescribed Epoetin dose, serum ferritin concentrations, and transferrin saturation levels. Iron use for the patients in this sample was analyzed. The data are from a random sample, not stratified by Network; thus, only national aggregate data are reported. No Network-specific or facility-specific analyses were conducted.

TABLE 3: Number of adult peritoneal dialysis patients in each Network in December 2000, sample size and response rate for the 2001 ESRD CPM Project.

Network	# Peritoneal Dialysis Patients in December 2000	Sample Size	# Acceptable Forms [^]	Response Rate %
1	1182	73	70	95.9
2	1698	87	70	80.5
3	1169	56	53	94.6
4	1019	51	42	82.4
5	1547	88	82	93.2
6	2343	140	135	96.4
7	1266	70	66	94.3
8	1545	87	84	96.6
9	2274	130	114	87.7
10	1111	67	56	83.6
11	1770	92	91	98.9
12	1351	61	59	96.7
13	1005	54	54	100.0
14	1713	84	81	96.4
15	1076	57	53	93.0
16	848	53	52	98.1
17	1506	85	79	92.9
18	1727	104	101	97.1
Total	26,150	1439	1342	93.3

[^] A form was considered acceptable if the patient was receiving peritoneal dialysis at least once during the six-month study period and had met the selection criteria for inclusion in the study.

TABLE 4: Characteristics of adult peritoneal dialysis patients in the 2001 ESRD CPM Project compared to those of all peritoneal dialysis patients in the US in 1999.

Patient Characteristic	2001 CPM Sample for Analysis		All US in 1999*	
	# ^	%	# in 1000s	%
TOTAL	1342	100	22.8	100
GENDER				
Men	675	50	11.6	51
Women	666	50	11.2	49
RACE				
American Indian/ Alaska Native	16	1	0.3	1.3
Asian/Pacific Islander	83	6	1.0	4
Black	368	27	6.0	26
White	808	60	15.0	66
Other/Unknown	67	5	0.5	2
ETHNICITY				
Hispanic	143	11	2.5	11
Non-Hispanic	1148	86	20.3	89
Other/Unknown	51	4	0	0
AGE GROUP (years)				
18-49	528	39	7.9**	35
50-59	305	23	4.9	22
60-64	161	12	2.3	10
65-69	130	10	2.4	11
70-79	177	13	3.7	16
80+	41	3	0.9	4
DIAGNOSIS				
Diabetes mellitus	480	36	8.1	36
Hypertension	268	20	5.0	22
Glomerulonephritis	254	19	4.2	18
Other/Unknown	340	25	5.4	24
DURATION of DIALYSIS (years)				
<0.5	299	22		
0.5-0.9	165	12		
1.0-1.9	278	21		
2.0+	587	44		

*USRDS: 2001 Annual Data Report, Bethesda, MD, National Institutes of Health, 2001. Tables D.4 and D.5.

[^] Subgroup totals may not equal 1342 due to missing data.

** For ages 20-49 years

Note: Percentages may not add up to 100% due to rounding.

Pediatric In-Center Hemodialysis Patients

Inclusion of a case for analysis required that data were available for at least one of the months in the three-month project period, with at least one paired pre- and post-dialysis BUN, at least one hemoglobin, and at least one serum albumin. Of the 516 patients, 435 patients were included in the sample for analysis (84% response rate) (TABLE 5).

For this report, each patient's mean value for the three-month project period was determined from the available data for the following items: Kt/V, dialysis session length, dialyzer KUf, blood pump flow rates, hemoglobin, transferrin saturation, serum ferritin concentration, prescribed Epoetin dose and route of administration, and serum albumin. Information on prescription and route of iron administration was collected. The data were collected on all pediatric patients aged ≥ 12 and < 18 years in the U.S. Only national aggregate data are reported. No Network-specific or facility-specific analyses were conducted.

G. REPORT FORMAT

This report describes the clinical performance measures and other findings for both the in-center hemodialysis patient sample and the peritoneal dialysis patient sample in separate sections, III and IV, respectively, for the following study period: October–December 2000 for the adult in-center hemodialysis patients, and October 2000–March 2001 for the adult peritoneal dialysis patients. This report also describes findings on clinical parameters of care for pediatric in-center hemodialysis patients (aged ≥ 12 and < 18 years) in the U.S. for October–December 2000 in Section V.

The national results are presented separately in tables by gender, race, ethnicity, age groups (for adult patients: 18–44, 45–54, 55–64, 65–74, and 75+ years of age, for pediatric patients: 12 to 15 and 16 to < 18 years of age), diagnosis of ESRD, and duration of dialysis. The diagnoses are categorized as diabetes mellitus (DM), hypertension (HTN), glomerulonephritis (GN), and other/unknown. In some instances clinical characteristics for patients in each Network area are also shown. Selected results are highlighted in figures. In addition, key findings from the 2001 CPM study period are compared to key findings from previous study periods.

TABLE 5: Characteristics of pediatric (≥ 12 and < 18 years) in-center hemodialysis patients in the 2001 ESRD CPM Project.

Patient Characteristic	2001 CPM Project	
	# ^A	%
TOTAL	435	(100)
GENDER		
Men	230	(53)
Women	203	(47)
RACE		
American Indian/ Alaska Native	2	(0.5)
Asian/Pacific Islander	12	(3)
Black	185	(43)
White	199	(46)
Other/Unknown	37	(9)
ETHNICITY		
Hispanic	101	(23)
Non-Hispanic	314	(72)
Other/Unknown	20	(5)
AGE GROUP (years)		
12 to 15	206	(47)
16 to < 18	229	(53)
DIAGNOSIS		
Congenital/Urologic	105	(24)
FSGS	75	(17)
Glomerulonephritis	70	(16)
SLE	21	(5)
Hypertension	14	(3)
Cystic Disease	3	(0.7)
Other/Unknown	147	(34)
DURATION of DIALYSIS (years)		
< 0.5	72	(17)
0.5–0.9	76	(17)
1.0–1.9	97	(22)
2.0+	186	(43)

^ASubgroup totals may not equal 435 due to missing data.

Note: Percentages may not add up to 100% due to rounding.

A form was considered acceptable if the patient met the selection criteria for inclusion in the study and if data were provided for at least one of the months in the fourth quarter of 2000 for the following items: 1) hemoglobin; 2) paired pre- and post-dialysis BUN values; and 3) serum albumin value.

Two or more monthly values for these clinical measures were available for 95% of patients for hemoglobin and 94% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 87% of patients. At least one monthly paired pre- and post-dialysis BUN value was available for 100% of patients, and two or more were available for 93%. Monthly paired pre- and post-dialysis BUN values were available for 78% of patients.

IN-CENTER HEMODIALYSIS PATIENTS

SYNOPSIS

- Purpose of Project: The ultimate purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in improving the care provided to ESRD patients. The specific purposes of the 2001 project were:

To compare the prevalence of important clinical measures and/or characteristics of adult (aged ≥ 18 years) in-center hemodialysis patients in the US in October–December 2000 to the prevalence of those characteristics in the last quarter of each year (October–December) 1993 through 1999;

AND, to identify opportunities to improve care for those patients.

- Method Used: A random sample of adult in-center hemodialysis patients who were alive on December 31, 2000, was selected (sample size 8,853).

ESRD facilities with one or more patients in the sample submitted completed data collection forms to their respective ESRD Network. The Networks then submitted a data file to ESRD Network 9/10 with the clinical information about these patients for the time period October, November, December 2000 for aggregation. This aggregated data file was then forwarded to CMS for initial analysis.

- Initial Findings: The sample for analysis consisted of 8,416 patients which was 95% of the original sample. Highlights from the initial findings are summarized below.

IMPROVEMENT OCCURRED

- 86% of the sampled patients were receiving dialysis with a delivered Kt/V ≥ 1.2 , an increase of two percentage points over late 1999 (FIGURE 2).
- 84% of Black patients and 87% of White patients were receiving dialysis with a mean delivered Kt/V ≥ 1.2 in October–December 2000. This was a one percentage point increase

for Black patients and a two percentage point increase for White patients from late 1999.

- 74% of patients had a mean hemoglobin ≥ 11 gm/dL in the last quarter of 2000 compared to 68% of the patients in the last quarter of 1999, a six percentage point increase from late 1999 to late 2000 (FIGURE 8).

- 10% of Black patients and 8% of White patients had a mean hemoglobin < 10 gm/dL in October–December 2000 compared to 15% and 10%, respectively, in October–December 1999.

OPPORTUNITIES TO IMPROVE

- 14% of patients did not have a mean Kt/V ≥ 1.2 during the three-month study period.

- 73% of incident patients and 70% of all patients were not dialyzed with an AV fistula during their last hemodialysis session October–December 2000.

- 53% of patients with an AV graft did not have this graft routinely monitored for the presence of stenosis during the three month study period.

- 26% of patients did not have a mean hemoglobin ≥ 11 gm/dL during the three month study period.

- 36% of patients prescribed Epoetin did not have a mean hemoglobin of 11–12.9 gm/dL during the three-month study period.

- 71% of patients did not have a mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method) during the three-month study period.

NEXT STEPS:

Network and CMS staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2002, 2003 and beyond. This Annual Report, as well as previous Annual Reports and Supplemental Reports may be found at www.hcfa.gov/quality/3m.htm.

III. ADULT IN-CENTER HEMODIALYSIS PATIENTS

This section describes the findings for the sampled adult in-center hemodialysis patients for selected CPMs and other quality indicators related to adequacy of dialysis, vascular access, anemia management and serum albumin. Each of these subsections is further broken down into three parts: (1) national findings for selected CPMs for October–December 2000 (the serum albumin information is not considered a CPM for this report); (2) a description of other quality indicators or data analysis for October–December 2000; and (3) a comparison of CPM and/or other quality indicators results or findings for October–December 2000 and previous study periods. A national random sample of adult (≥ 18 years) in-center hemodialysis patients, stratified by Network, who were alive on December 31, 1999, was selected ($n=8853$). 8416 patients (95%) were included in the sample for analysis.

A. ADEQUACY OF HEMODIALYSIS

1. CPM Findings for October–December 2000

Data to assess five hemodialysis adequacy CPMs were collected in 2001. The time period from which these data were abstracted was October–December 2000. Results for three of these CPMs are included in this section of the report (Hemodialysis Adequacy CPMs I–III).

Hemodialysis Adequacy CPM I — The patient's delivered dose of hemodialysis is measured at least once per month.

FINDING: 80% of adult in-center hemodialysis patients in the sample for analysis had documented measurements of hemodialysis adequacy (URR and/or Kt/V) for each month during the three-month study period (October–December 2000). These measurements were recorded in the patient's chart, not calculated from individual data points. An additional 13% of the patients in the sample for analysis had documented adequacy measurements for two out of the three months, and another six percent of the patients had documented adequacy measurements for one of the three months.

Hemodialysis Adequacy CPM II — The patient's delivered dose of hemodialysis recorded in the patient's chart is calculated by using formal urea kinetic modeling (UKM) or the Daugirdas II formula (for Kt/V) (23).

FINDING: 52% of adult in-center hemodialysis patients in the sample for analysis had each delivered hemodialysis dose reported as Kt/V calculated using formal UKM or the Daugirdas II formula.

Hemodialysis Adequacy CPM III — The patient's delivered dose of hemodialysis calculated from data points on the data collection form (monthly measurement averaged over the three-month study period) is Kt/V ≥ 1.2 . This CPM is calculated on the subset of patients who had been on hemodialysis for six months or longer and who were dialyzing three times per week ($n=6250$).

FINDING: For the last quarter of 2000, 91% of the adult in-center hemodialysis patients who met the inclusion criteria (only those patients who had been on hemodialysis for six months or longer and who were dialyzing three times per week [$n=6250$]) had a mean delivered hemodialysis dose of Kt/V ≥ 1.2 .

2. Other Hemodialysis Adequacy Findings for October–December 2000

NOTE: The following findings apply to all adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The mean (\pm SD) delivered calculated Kt/V of all adult in-center hemodialysis patients in the sample for analysis in the last quarter of 2000 was 1.49 (± 0.29) (FIGURE 3). The distribution of Kt/V values for these patients is shown in Figure 15. The mean (\pm SD) delivered calculated URR for this population was 70.6% ($\pm 7.2\%$). 82% of patients had a mean delivered URR $\geq 65\%$. The mean delivered Kt/V and the percent of patients with mean delivered Kt/V ≥ 1.2 and Kt/V ≥ 1.25 for gender, race, ethnicity, age, diagnosis, duration of dialysis, quintile of post-dialysis body weight, access type, and selected clinical parameters are shown in Table 6.

The percent of patients in the sample for analysis with at least one calculated Kt/V measure available ($n=8276$) who received adequate hemodialysis, defined as a mean delivered Kt/V ≥ 1.2 , approximately equivalent to URR $\geq 65\%$ (2) in the last quarter of 2000 was 86% (TABLE 6, FIGURE 2).

The percent of patients receiving hemodialysis with a mean delivered Kt/V ≥ 1.2 was higher for women than for men, higher for Whites than for Blacks, higher for Hispanics than for non-Hispanics, higher for patients dialyzing six months or longer than for patients dialyzing less than six months, higher for patients in lower quintiles of body weight, and higher for patients ≥ 65 years of age than for younger patients (TABLE 6).

A higher percent of patients with mean hemoglobin ≥ 11 gm/dL and mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP) had a mean Kt/V ≥ 1.2 compared to patients with lower mean hemoglobin and serum albumin values. A higher percent of patients dialyzed with an AV fistula or an AV graft had a mean delivered Kt/V ≥ 1.2 compared to patients dialyzed with a catheter (87% and 92% vs. 75% respectively) (TABLE 6).

Figure 15: Distribution of mean delivered calculated Kt/V values for adult in-center hemodialysis patients, October–December 2000. 2001 ESRD CPM Project.

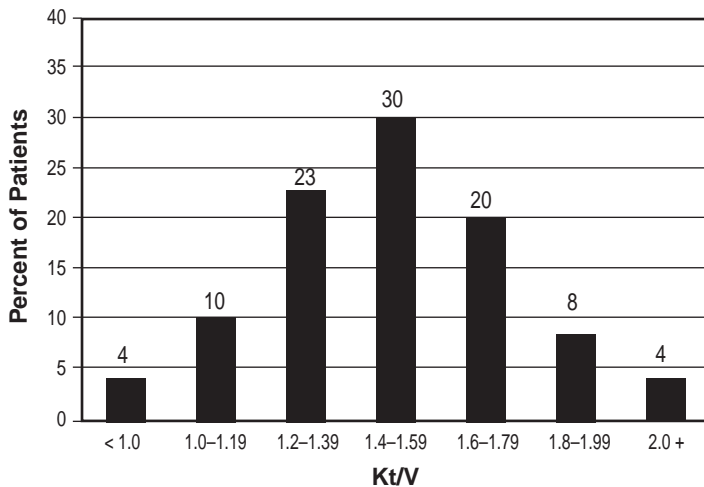


Figure 16: Distribution of mean dialysis session length (minutes) for adult in-center hemodialysis patients, by access type, October–December 2000. 2001 ESRD CPM Project.

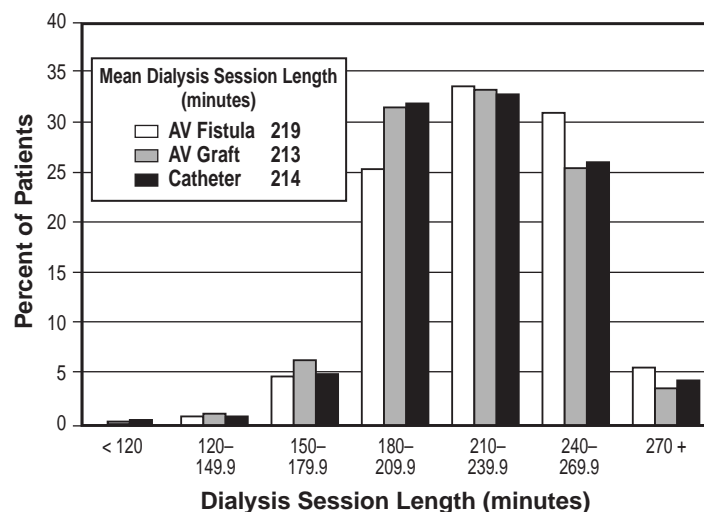


TABLE 6: Mean delivered calculated Kt/V and percent of adult in-center hemodialysis patients with mean delivered calculated Kt/V ≥ 1.2 and ≥ 1.25 by patient characteristics, October–December 2000. 2001 ESRD CPM Project.

Patient Characteristics	Mean Kt/V	% Kt/V ≥ 1.2	%Kt/V ≥ 1.25
TOTAL	1.49	86	83
GENDER			
Men	1.43	82	77
Women	1.56	91	88
RACE			
American Indian/ Alaska Native	1.61	92	91
Asian/Pacific Islander	1.62	93	90
Black	1.46	84	80
White	1.50	87	84
Other/Unknown	1.55	88	85
ETHNICITY			
Hispanic	1.54	88	85
Non-Hispanic	1.49	86	82
AGE GROUP (years)			
18–44	1.46	82	78
45–54	1.45	83	79
55–64	1.48	85	81
65–74	1.52	89	86
75+	1.55	90	87
DIAGNOSIS			
Diabetes mellitus	1.47	84	80
Hypertension	1.51	88	85
Glomerulonephritis	1.48	85	82
Other/Unknown	1.52	89	86
DURATION of DIALYSIS (years)			
< 0.5	1.34	66	60
0.5–0.9	1.45	83	76
1.0–1.9	1.49	88	85
2.0+	1.54	91	88
QUINTILE POST-DIALYSIS BODY WEIGHT (kg)			
32.2–58.1	1.66	95	93
58.2–67.4	1.56	92	89
67.5–76.4	1.48	88	85
76.5–88.9	1.43	83	79
89.0–204.6	1.33	72	67
ACCESS TYPE			
AV Fistula	1.48	87	84
AV Graft	1.55	92	89
Catheter	1.39	75	69
MEAN HEMOGLOBIN			
≥ 11 gm/dL	1.51	88	85
< 11 gm/dL	1.45	81	76
MEAN SERUM ALBUMIN			
$\geq 3.5/3.2$ gm/dL*	1.50	87	84
< 3.5/3.2 gm/dL	1.47	82	78

* BCG/BCP = bromocresol green/bromocresol purple laboratory methods

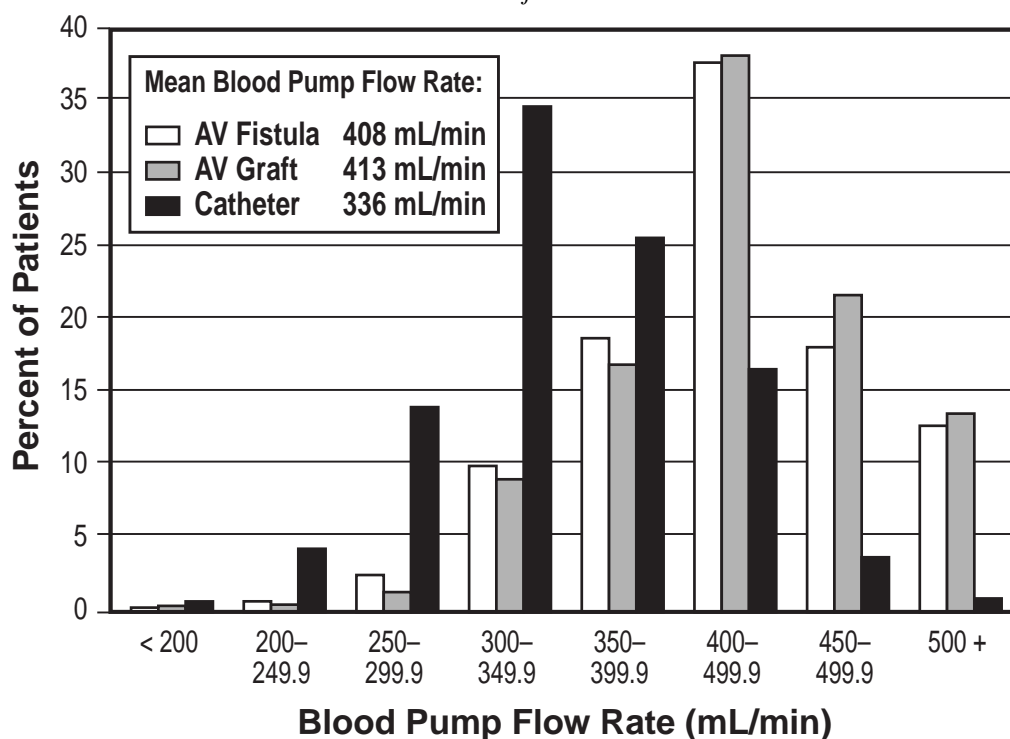
The mean (\pm SD) dialysis session length was 215 minutes (\pm 30 minutes). The mean dialysis session length was somewhat longer for men than for women (223 minutes vs. 207 minutes), for Blacks than for Whites (220 minutes vs. 213 minutes), and for patients dialyzing six months or longer compared to patients dialyzing less than six months (216 minutes vs. 209 minutes). Patients in the highest quintile of post-dialysis body weight (kg) had longer dialysis session lengths compared to patients in the lowest quintile (236 minutes vs. 199 minutes). The mean dialysis session length was 219 minutes for patients dialyzed with an AVF, 213 minutes for patients with either a synthetic or bovine graft, and 214 minutes for patients with a catheter access during October-December 2000 (FIGURE 16).

The delivered mean (\pm SD) blood pump flow rate 60 minutes into the dialysis session was 408 mL/min (\pm 63.3 mL/min) for patients with an AVF, 413 mL/min (\pm 61.2 mL/min) for patients with either a synthetic or bovine graft, and 336 mL/min (\pm 60.9

mL/min) for patients with a catheter access during October - December 2000 (FIGURE 17). Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (24). The difference between prescribed and actual blood flow to the dialyzer increases with more negative pre-pump pressures. This is particularly true for catheters where differences between delivered and prescribed blood flow to the dialyzer of 25% or more may exist at prescribed blood pump flow rates of 400 mL/min or more (25).

The percent of patients who received adequate hemodialysis varied significantly from one geographic region to another. Table 7 shows, by gender, race, and ethnicity, the percent of patients who received hemodialysis with a mean delivered Kt/V \geq 1.2 in each Network area. The percent of all patients with mean delivered Kt/V \geq 1.2 ranged from 83% to 92% among the 18 Networks (FIGURES 18, 19).

Figure 17: Distribution of mean delivered blood pump flow rates 60 minutes into the dialysis session for adult in-center hemodialysis patients, by access type, October–December 2000. 2001 ESRD CPM Project.



Note: Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (24). This is particularly true for catheters where differences between delivered and prescribed blood flow to the dialyzer of 25% or more may exist at prescribed blood pump flow rates of 400 mL/min or more (25).

TABLE 7: *Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered Kt/V ≥ 1.2, by gender, race, ethnicity and Network, October-December 2000. 2001 ESRD CPM Project.*

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	88	85	84	87	86	85	84	89	86	85	85	87	86	92	90	89	83	84	86
GENDER																			
Men	85	82	79	83	80	79	81	86	83	79	79	83	82	87	87	86	76	77	82
Women	92	89	91	92	92	90	88	92	90	91	90	92	90	96	94	93	90	91	91
RACE																			
Black	89	80	79	85	85	84	81	89	84	84	78	88	84	89	91	74	75	80	84
White	87	87	91	89	86	85	87	90	87	86	87	86	89	92	90	89	81	82	87
ETHNICITY																			
Hispanic	87	83	85	*	100	*	81	*	*	89	94	100	87	93	89	92	90	84	88
Non-Hispanic	88	85	84	87	85	84	85	89	86	85	84	87	86	91	90	89	81	84	86

Note: A delivered Kt/V of 1.2 does not necessarily correlate with a delivered URR of 65%.
* Value suppressed because n ≤ 10.

Figure 18: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered Kt/V ≥ 1.2, by Network, October–December 2000. 2001 ESRD CPM Project.

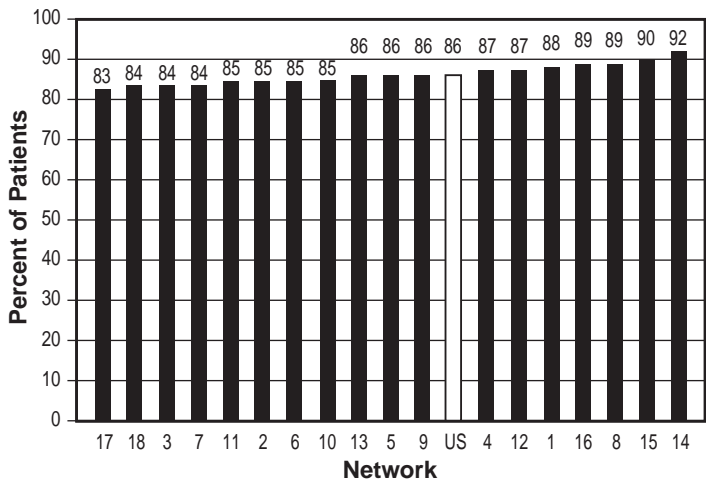
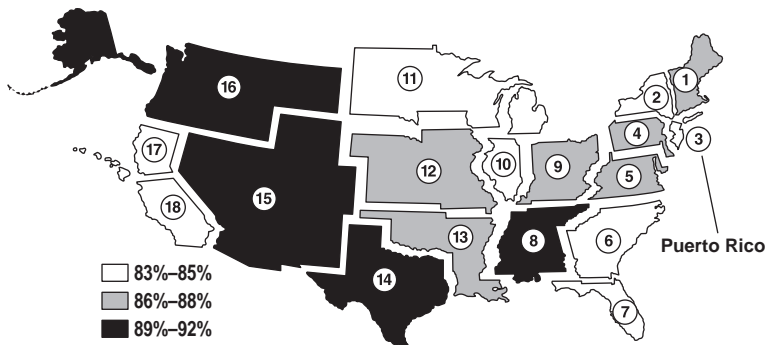


Figure 19: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered Kt/V ≥ 1.2, by Network, October–December 2000. 2001 ESRD CPM Project.



3. CPM and other Findings for October–December 2000 compared to previous study periods

Note: The following findings apply to all adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The average (\pm SD) delivered Kt/V in October–December 2000 was 1.49 (\pm 0.29), an increase from previous study years (FIGURE 3). The percent of patients receiving dialysis with a mean delivered Kt/V \geq 1.2 increased significantly from 84% in late 1999 to 86% in late 2000 (FIGURE 2). This significant improvement occurred for both men and women and for White and Black patients (FIGURES 20 and 21).

Figure 20: Percent of adult male in-center hemodialysis patients with mean delivered Kt/V ≥ 1.2, by race, October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.

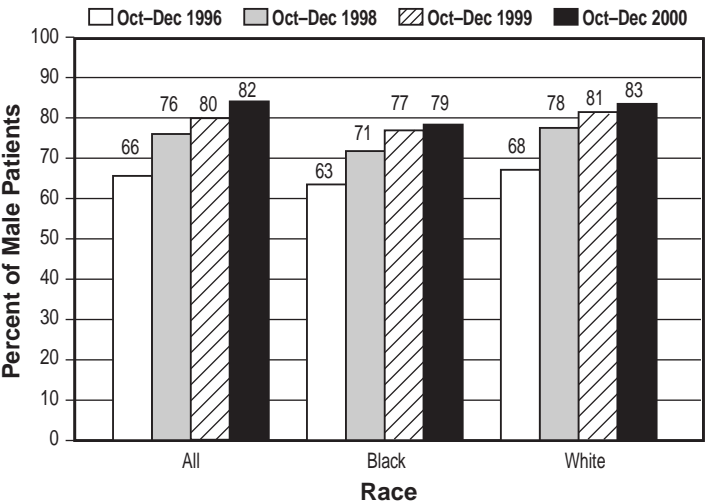


Figure 21: Percent of adult female in-center hemodialysis patients with mean delivered Kt/V ≥ 1.2, by race, October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.

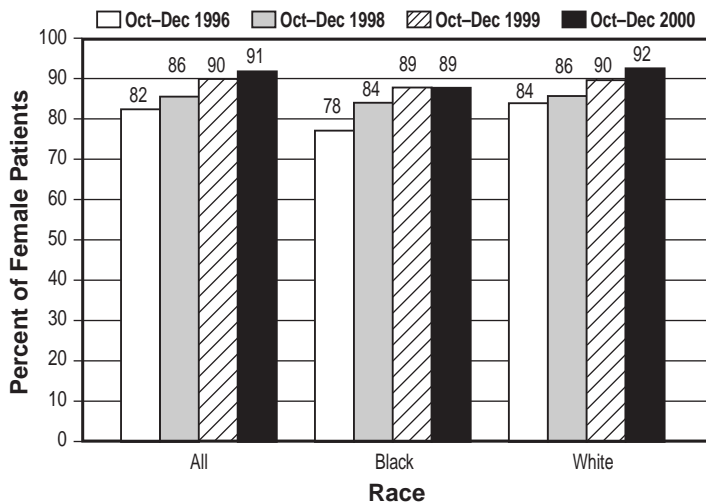
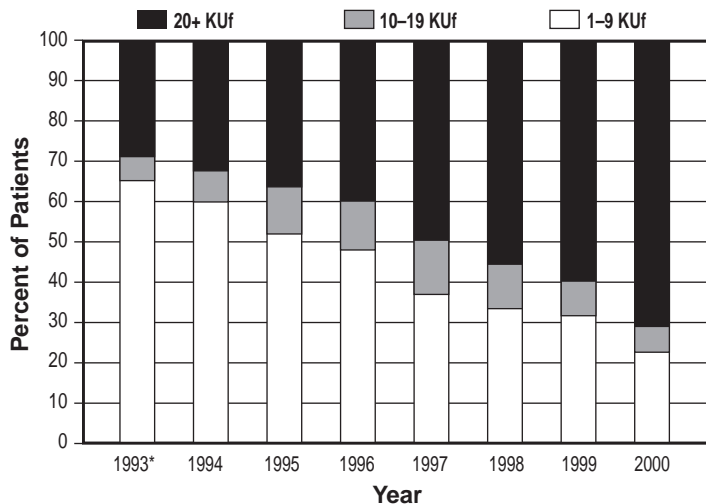


Figure 22 shows the percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category October–December 2000, compared to previous study years. The percent of patients dialyzed with a dialyzer with a KUF ≥ 20 mL/mmHg/hr increased from approximately 30% in late 1993 to approximately 70% in late 2000.

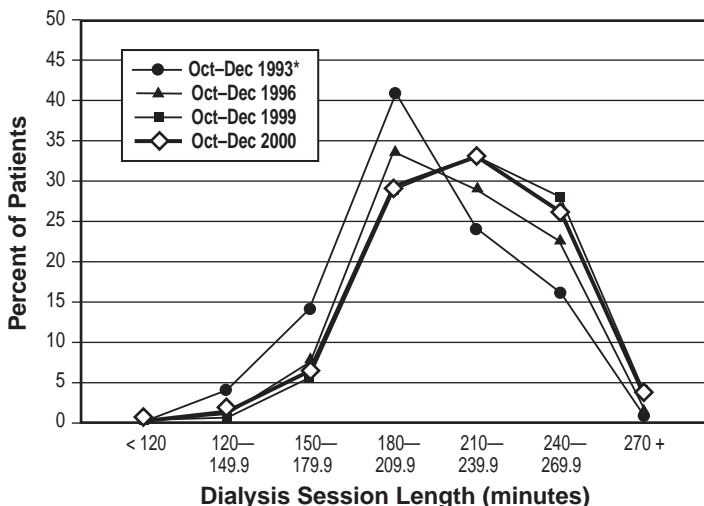
Figure 23 shows a trend for slight increases in dialysis session lengths from late 1993 to late 2000.

Figure 22: Percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category, October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators Project assessment (October–December 1993); all Network areas participated in subsequent years.

Figure 23: Distribution of mean dialysis session length (minutes), October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators Project assessment (October–December 1993); all Network areas participated in subsequent years.

B. VASCULAR ACCESS

1. CPM Findings for October–December 2000

Data to assess three vascular access CPMs were collected in 2001. The time period from which these data were abstracted was October–December 2000. Results for these CPMs are included in this report.

Vascular Access CPM I — A primary arterial venous fistula (AVF) should be the access for at least 50% of all new patients initiating hemodialysis. A native AVF should be the primary access for 40% of all prevalent patients undergoing hemodialysis.

FINDING: 27% of incident patients (initiating their most recent course of hemodialysis, on or between January 1, 2000, and August 31, 2000, [n = 1519]) were dialyzed using an AVF on their last hemodialysis session during October–December 2000.

30% of all patients in the sample for analysis were dialyzed using an AVF during their last hemodialysis session October–December 2000.

Vascular Access CPM II — Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters (continuously for 90 days or longer) as their permanent chronic dialysis access.

FINDING: 17% of all patients in the sample for analysis were dialyzed with a chronic catheter continuously for 90 days or longer during October–December 2000.

Vascular Access CPM III — A patient's AV graft should be routinely monitored for stenosis. (See Vascular Access CPM III in Appendix 1 for a list of techniques and frequency of monitoring used to screen for the presence of stenosis).

FINDING: 47% of patients with an AV graft (n=3806) had this graft routinely monitored for the presence of stenosis during October–December 2000.

TABLE 8: Vascular access type for incident[^] and all adult in-center hemodialysis patients during the last hemodialysis session of the study period, by selected patient characteristics, October-December 2000. 2001 ESRD CPM Project.

Patient Characteristic	Incident (n=1519)			Prevalent (n=8416)		
	AVF %	Graft %	Catheter %	AVF %	Graft %	Catheter %
TOTAL	27	37	37	30	46	24
GENDER						
Men	37	32	31	39	40	20
Women	16	41	43	19	52	29
RACE						
American Indian/ Alaska Native	*	*	*	37	43	21
Asian/Pacific Islander	30	36	34	33	50	17
Black	26	42	32	26	52	22
White	27	33	40	32	41	27
Other/Unknown	30	42	28	35	43	23
ETHNICITY						
Hispanic	30	43	27	32	47	21
Non-Hispanic	26	36	38	29	46	25
AGE GROUP (years)						
18-44	38	26	36	40	36	24
45-54	34	34	32	34	45	21
55-64	29	38	33	28	49	22
65-74	20	42	38	26	49	25
75+	22	37	42	24	48	29
DIAGNOSIS						
Diabetes Mellitus	23	41	36	24	50	25
Hypertension	31	39	31	31	48	21
Glomerulonephritis	33	29	38	37	40	23
Other/Unknown	29	28	43	35	38	27
DURATION of DIALYSIS (years)						
< 0.5	18	33	49	17	27	56
0.5-0.9	31	37	32	30	38	32
1.0-1.9	N/A	N/A	N/A	33	47	20
2.0+	N/A	N/A	N/A	31	52	17

[^]An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2000 and August 31, 2000.

Note: Percentages may not add up to 100% due to rounding.

*Value suppressed because n ≤ 10.

2. Other Vascular Access Findings for October-December 2000

27% of incident and 30% of prevalent patients in the sample for analysis were dialyzed with an AV fistula on their last hemodialysis session during October–December 2000 (TABLE 8). More men, Whites, patients 18-44 years old, patients with causes of ESRD other than diabetes mellitus, and patients dialyzing six months or longer were dialyzed with an AV fistula compared to women, Blacks, patients older than 44 years, patients with diabetes mellitus as the cause of ESRD, and patients dialyzing less than six months (TABLE 8). With the exception of patients 18-44 years old, all patient groups examined were below the current DOQI recommendation of 40% of prevalent patients having an AV fistula as their vascular access(5) (FIGURE 24). The percent of prevalent patients with a catheter as their vascular access, by several patient characteristics, is shown in Figure 25. More women, Whites, and patients in the lowest quartile of post-dialysis BMI had a catheter access compared to men, Blacks, and patients in higher quartiles of post-dialysis BMI.

There was wide geographic variation in the percent of all patients dialyzed with an AVF; the percent ranged from 22% to 42% among the 18 Network areas (FIGURE 26, TABLE 9). This geographic variation in AVF use was also noted for incident patients, ranging from 17% to 39% among the 18 Network areas (FIGURE 27).

The percent of patients dialyzed with a catheter exhibited geographic variation, ranging from 16% to 30% among the 18 Network areas (FIGURE 28, TABLE 10). Chronic catheter use, defined for this report as catheter use continuously for 90 days or longer, ranged from 11% to 23% across the 18 Network areas (FIGURE 29).

Figure 24: Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2000, by patient characteristics. 2001 ESRD CPM Project.

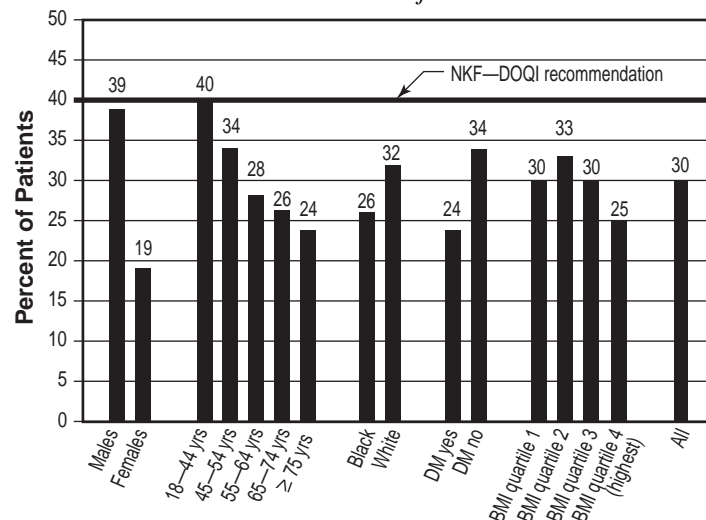


Figure 25: Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October–December 2000, by patient characteristics. 2001 ESRD CPM Project.

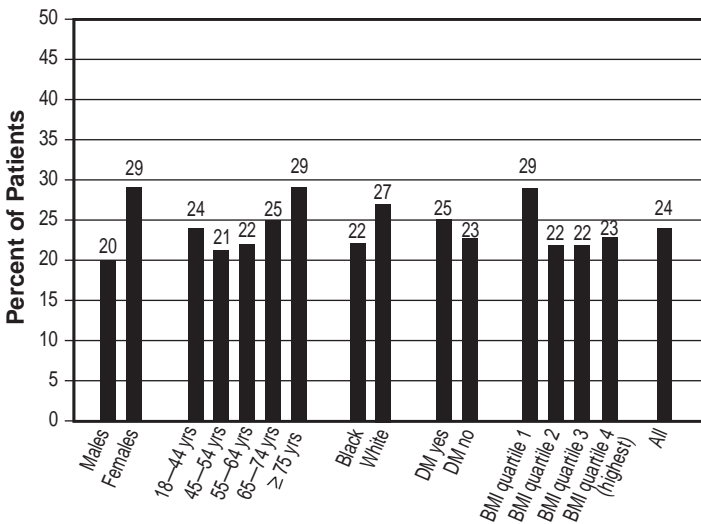


Figure 26: Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October–December 2000, by Network. 2001 ESRD CPM Project.

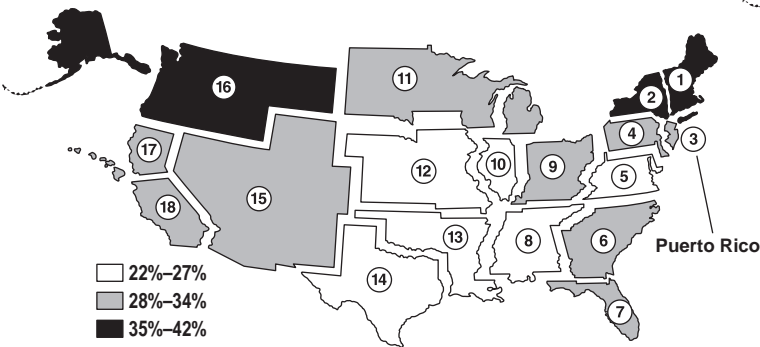
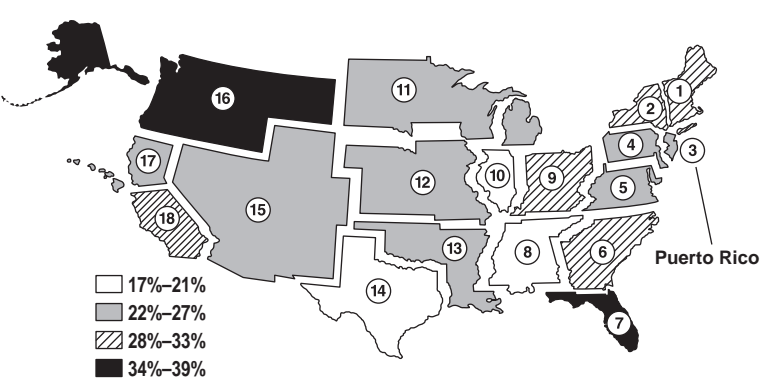


Figure 27: Percent of incident* adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October–December 2000, by Network. 2001 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2000 and August 31, 2000.

Figure 28: Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October–December 2000, by Network. 2001 ESRD CPM Project.

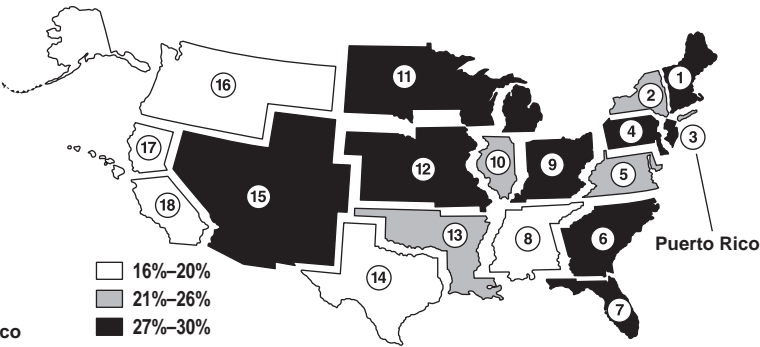


Figure 29: Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October–December 2000, by Network. 2001 ESRD CPM Project.

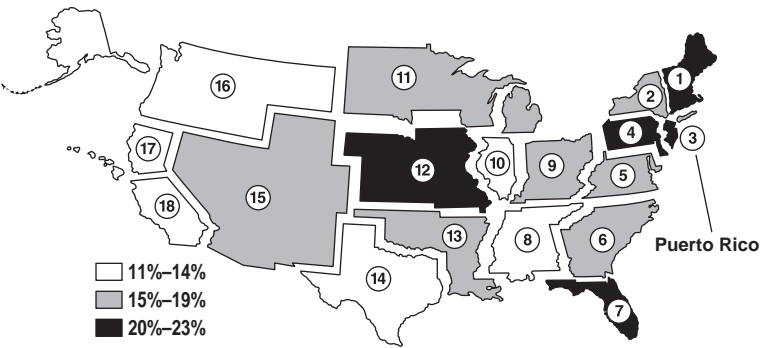


TABLE 9: *Percent of all adult in-center hemodialysis patients with an AV fistula access on their last hemodialysis session during October–December 2000, by gender, race, ethnicity, age, and Network. 2001 ESRD CPM Project.*

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	42	40	29	32	27	28	31	22	28	27	28	26	25	22	33	41	29	32	30
GENDER																			
Men	49	51	35	40	36	40	42	31	37	40	38	35	36	31	41	52	37	42	39
Women	32	25	21	24	16	16	17	15	19	14	18	17	15	12	24	28	21	23	19
RACE																			
Black	37	36	23	29	27	26	29	21	23	24	28	19	26	17	30	57	28	28	26
White	42	45	30	34	26	32	32	26	31	30	27	31	24	24	32	40	28	34	32
ETHNICITY																			
Hispanic	*	44	42	*	*	*	30	*	*	36	*	*	*	25	36	*	17	35	32
Non-Hispanic	44	39	23	32	26	28	32	22	28	25	28	26	25	21	32	43	32	31	29
AGE GROUP (years)																			
18-44	55	51	32	39	40	35	39	39	43	37	37	37	31	30	45	54	38	51	40
45-54	43	47	45	36	27	30	35	30	28	32	36	31	26	31	33	47	42	32	34
55-64	40	39	32	26	25	25	36	22	31	26	26	27	32	16	26	30	25	33	28
65-74	41	33	23	34	22	26	27	15	24	24	21	23	23	18	31	39	26	26	26
75+	36	35	19	30	19	23	25	*	20	19	25	17	16	*	32	38	22	22	24

* Value suppressed because $n \leq 10$.

TABLE 10: Percent of all adult in-center hemodialysis patients with a catheter access on their last hemodialysis session during October–December 2000, by gender, race, ethnicity, age, and Network. 2001 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	28	22	30	28	26	27	30	16	30	26	28	28	23	19	27	18	18	18	24
GENDER																			
Men	26	19	22	25	24	19	25	13	21	21	21	26	20	17	26	15	16	15	20
Women	31	27	39	30	30	33	36	20	40	31	34	30	27	22	29	22	20	21	29
RACE																			
Black	25	19	29	18	22	27	28	14	25	24	22	27	19	18	20	*	19	13	22
White	28	26	33	33	35	28	31	19	33	28	30	29	30	20	29	19	18	20	27
ETHNICITY																			
Hispanic	*	*	21	*	*	*	37	*	*	27	*	*	*	17	30	*	21	16	21
Non-Hispanic	26	24	34	28	27	27	28	17	30	27	27	28	24	20	26	18	17	19	25
AGE GROUP (years)																			
18-44	17	17	30	31	24	32	29	18	25	32	33	32	23	21	22	16	22	15	24
45-54	31	15	28	*	20	22	29	12	27	30	35	27	17	18	20	17	*	17	21
55-64	32	22	24	29	28	24	28	14	31	18	26	25	18	16	29	21	20	14	22
65-74	28	23	32	28	30	29	26	17	31	26	23	30	26	20	30	20	17	19	25
75+	29	32	35	31	30	28	37	22	35	28	26	27	33	23	33	17	19	23	29

* Value suppressed because $n \leq 10$.

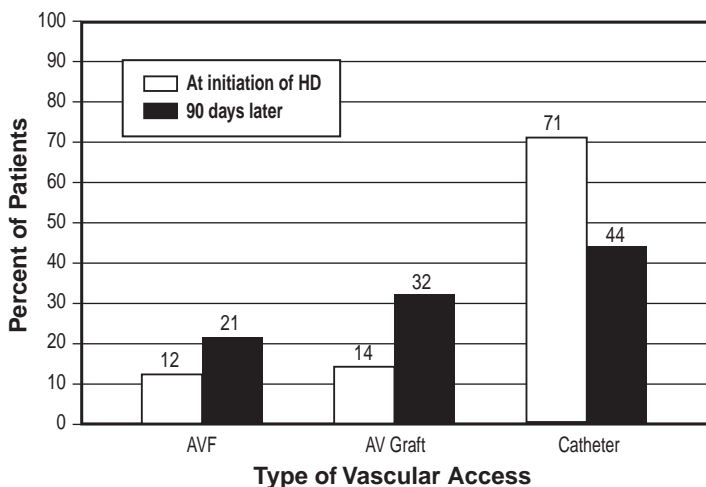
Table 11 depicts the odds ratio (95% CI) for a patient having an AV fistula as his/her vascular access on his/her last hemodialysis session during October-December 2000 by selected patient characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example, a male has an almost three times greater chance of having an AV fistula for his vascular access compared to a female (without controlling for any other variables).

24% (n=2055) of all patients in the sample for analysis were dialyzed with a catheter during their last hemodialysis session of the study period (TABLE 8). A higher percent of women compared to men, Whites compared to Blacks, patients aged 75 years or more compared to younger patients, and patients dialyzing less than six months compared to those patients dialyzing six months or longer were dialyzed with a catheter (TABLE 8). The most common reasons for catheter placement were: no fistula or graft surgically created (27%) and the fistula or graft was maturing, not ready to cannulate (24%) (TABLE 12). 16% of patients were not candidates for fistula or graft placement as all sites had been exhausted.

48% of patients with an AV fistula or graft (n=6322) had their vascular access monitored for stenosis during the study period. For this subset of patients, 63% were monitored with dynamic venous pressure, 15% with static venous pressure, 10% with the dilution technique, 7% with Color-Flow Doppler, and 20% with "Other" techniques (groups not mutually exclusive).

12% of incident patients had an AV fistula as their vascular access upon initiation of a maintenance course of hemodialysis; 21% of incident patients had an AV fistula as their vascular access 90 days later (FIGURE 30). 71% of incident patients had a catheter as their vascular access upon initiation of a maintenance course of hemodialysis; 44% of incident patients had a catheter as their vascular access 90 days later.

Figure 30: Percent of incident* adult in-center hemodialysis patients with a catheter as their vascular access upon initiation of a maintenance course of hemodialysis, and 90 days later, October-December 2000. 2001 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2000 and August 31, 2000.

TABLE 11: Independent logistic regression analyses by selected patient and clinical characteristics to predict odds ratio (95% CI) for having an AV fistula access, October-December 2000. 2001 ESRD CPM Project.

Characteristic	Odds Ratio (95% CI)
GENDER	
Male	2.7 (2.5, 3.0)
Female (referent)	
RACE	
White	1.3 (1.2, 1.5)
Black (referent)	
AGE GROUP (years)	
18-44	1.8 (1.6, 2.0)
45+ (referent)	
DIABETES MELLITUS	
Yes	0.65 (0.59, 0.72)
No (referent)	
QUARTILE POST-DIALYSIS BMI	
Quartile 2	1.3 (1.1, 1.5)
Quartile 3	1.5 (1.3, 1.7)
Quartile 4 (highest)	1.3 (1.1, 1.5)
(Quartile 1 = referent)	

TABLE 12: Reasons for catheter placement in adult in-center hemodialysis patients on their last hemodialysis session during October-December 2000. 2001 ESRD CPM Project.

Reason	n	(%)
TOTAL	2055	(100)
No fistula or graft surgically created in this patient's body at this time	549	(27)
Fistula or graft maturing, not ready to cannulate	485	(24)
All fistula or graft sites in this patient's body have been exhausted	323	(16)
Temporary interruption of fistula or graft due to clotting or revisions	294	(14)
Peripheral vascular disease	136	(7)
Patient size too small for AV fistula or graft	18	(1)
Renal transplantation scheduled	18	(1)
Other	219	(11)
Unkown	13	(0.6)

*Note: Percentages may not add up to 100% due to rounding.

3. CPM and Other Findings for October-December 2000 compared to previous study periods.

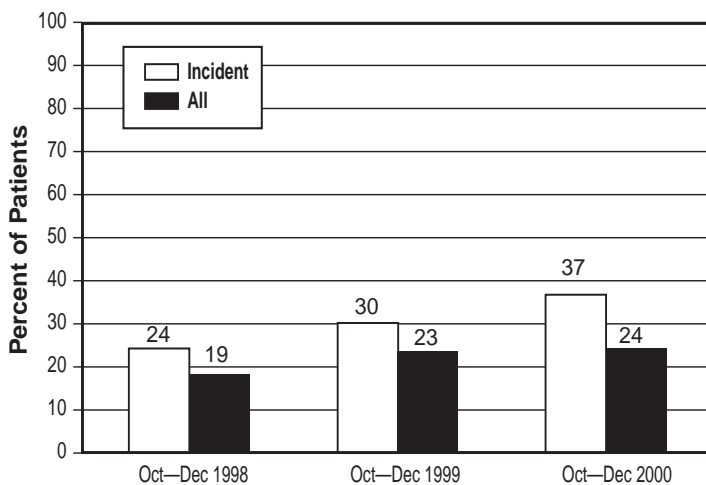
More patients were dialyzed with a catheter on their last hemodialysis session during October-December 2000 compared to October-December 1998 and 1999 (24% compared to 19% and 23%, respectively) (FIGURES 4, 31). A similar pattern was noted for incident patients, with 37% of incident patients in late 2000 dialyzed with a catheter on their last hemodialysis session compared to 24% in late 1998 and 30% in late 1999 (FIGURE 31).

There was some change in the percent of all patients dialyzed with an AV fistula on their last hemodialysis session from late 1998 to late 2000 (26% vs. 30%, respectively) (FIGURE 32). 26% of incident patients were dialyzed with an AV fistula on their last hemodialysis session in late 1998 compared to 27% in late 2000 (FIGURE 32).

14% of all patients were dialyzed with a chronic catheter continuously for 90 days or longer during late 1998 and 1999, compared to 17% of all patients during October-December 2000 (FIGURE 4).

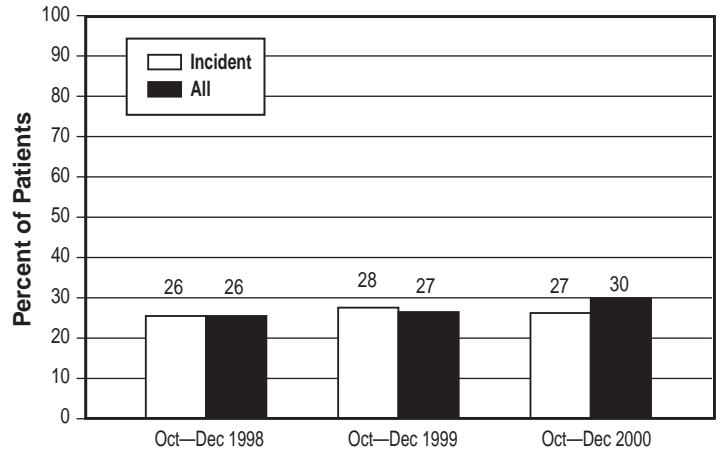
There has been little change in the percent of different types of stenosis monitoring for patients with either an AV fistula or an AV graft as their vascular access from late 1998 to late 2000 (FIGURE 33).

Figure 31: Percent of adult in-center hemodialysis patients (all and incident*) dialyzed with a catheter as their access on their last hemodialysis session during October-December 2000 compared to previous study periods. 2001 ESRD CPM Project.



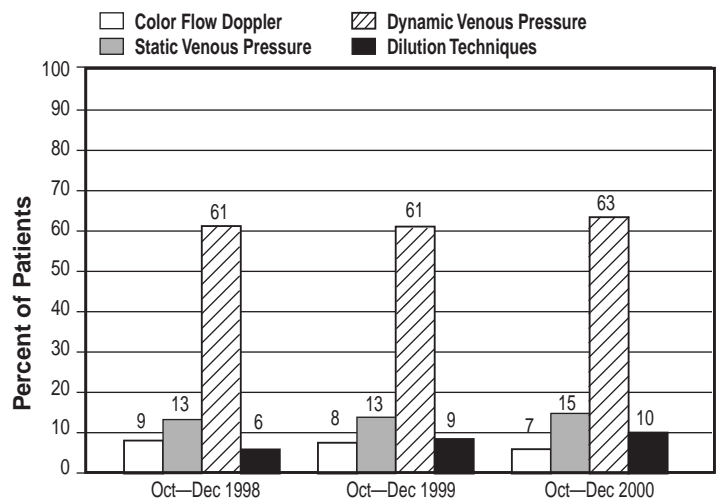
*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1 and August 31, of the study year.

Figure 32: Percent of adult in-center hemodialysis patients (all and incident*) dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2000 compared to previous study periods. 2001 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1 and August 31, of the study year.

Figure 33: Types of stenosis monitoring reported for adult in-center hemodialysis patients with either an AV fistula or an AV graft as their vascular access on their last hemodialysis session during October-December 2000 compared to previous study periods. 2001 ESRD CPM Project.



See Appendix 1 for a complete description of the types of stenosis monitoring.

C. ANEMIA MANAGEMENT

1. CPM and Other Findings for October–December 2000

Data to assess three anemia management CPMs were collected in 2001. The time period from which these data were abstracted was October–December 2000.

Anemia Management CPM I — The target hemoglobin is 11–12 gm/dL. Patients with a mean hemoglobin > 12 gm/dL and not prescribed Epoetin were excluded from analysis for this CPM.

FINDING: For the last quarter of 2000, 38% of the in-center hemodialysis patients who met the inclusion criteria (n=8172) had a mean hemoglobin 11–12.0 gm/dL.

Anemia Management CPM IIa — For all anemic patients (hemoglobin < 11 gm/dL) or patients prescribed Epoetin, the percent transferrin saturation and the serum ferritin concentration are assessed (measured) at least once in a three-month period.

FINDING: For the last quarter of 2000, 91% of the in-center hemodialysis patients who met the inclusion criteria (n=8142) had at least one documented (measured) transferrin saturation value and at least one documented (measured) serum ferritin concentration value during the study period.

Anemia Management CPM IIb — For all anemic patients (hemoglobin < 11 gm/dL) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation $\geq 20\%$ were documented during the three-month study period.

FINDING: For the last quarter of 2000, 71% of the in-center hemodialysis patients who met the inclusion criteria (n=8142) had at least one documented transferrin saturation $\geq 20\%$ and at least one documented serum ferritin concentration ≥ 100 ng/mL during the study period.

Anemia Management CPM III — All anemic patients (hemoglobin < 11 gm/dL), or patients prescribed Epoetin, and with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was $\geq 50\%$ or the mean serum ferritin concentration was ≥ 800 ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

FINDING: 73% of the in-center hemodialysis patients who met the inclusion criteria (n=2955) were prescribed intravenous iron in at least one month during October–December 2000.

2. Other Anemia Management Findings for October–December 2000

NOTE: The following findings apply to all the adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The distributions of mean hemoglobin values are shown in Figure 34 for both Black and White patients. The mean (\pm SD) hemoglobin value for all patients in this sample was 11.6 gm/dL (± 1.2 gm/dL). The mean hemoglobin values for gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters are shown in Table 13.

The mean hemoglobin value was lower for women, Blacks, non-Hispanics, patients dialyzing less than six months, patients with diabetes mellitus as the cause of ESRD, and patients 18–44 years old compared to men, Whites, Hispanics, patients dialyzing six months or longer, patients with other causes of ESRD, and patients older than 44 years.

The mean hemoglobin value was higher for patients with a mean Kt/V ≥ 1.2 compared to patients with a mean Kt/V < 1.2, higher for patients with higher mean serum albumin values, and higher for patients dialyzed with an AV fistula or AV graft compared to patients dialyzed with a catheter. (TABLE 13).

Figure 34: Distribution of mean hemoglobin values for adult in-center hemodialysis patients in the US, by race, October–December 2000. 2001 ESRD CPM Project.

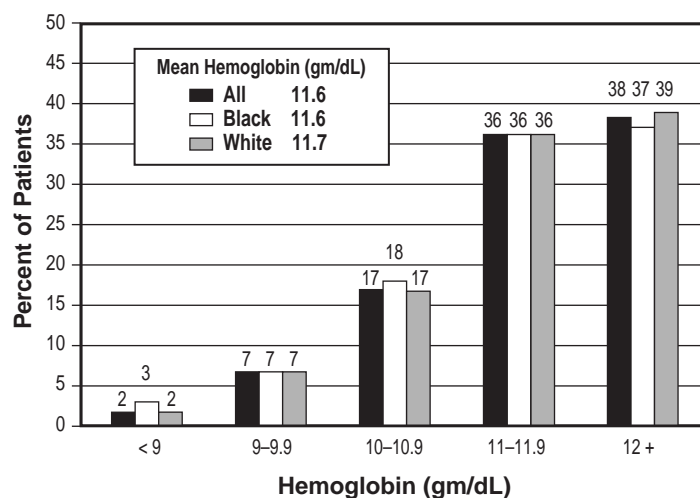


TABLE 13: Mean hemoglobin values (gm/dL) for adult in-center hemodialysis patients in the US, by patient characteristics, October–December 2000. 2001 ESRD CPM Project.

Patient Characteristic	Mean Hemo-globin (gm/dL)	Percent of patients with Hemoglobin values (gm/dL)				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
TOTAL	11.6	2	7	17	36	38
GENDER						
Men	11.7	2	6	16	35	41
Women	11.5	2	7	19	37	35
RACE						
American Indian/ Alaska Native	11.6	*	*	23	33	37
Asian/Pacific Islander	11.6	*	5	18	38	36
Black	11.6	3	7	18	36	37
White	11.7	2	7	17	36	39
Other/Unknown	11.6	3	7	18	34	38
ETHNICITY						
Hispanic	11.7	2	6	16	35	40
Non-Hispanic	11.6	2	7	18	36	38
AGE GROUP (years)						
18-44	11.5	4	8	18	31	38
45-54	11.7	3	6	16	36	39
55-64	11.6	2	7	17	36	38
65-74	11.6	2	7	18	35	38
75+	11.7	1	5	17	39	38
DIAGNOSIS						
Diabetes mellitus	11.6	2	8	18	35	37
Hypertension	11.7	2	6	17	36	40
Glomerulonephritis	11.7	3	4	17	39	38
Other/Unknown	11.7	3	6	17	34	40
DURATION of DIALYSIS (years)						
< 0.5	11.0	8	16	24	26	26
0.5-0.9	11.7	2	6	16	34	42
1.0-1.9	11.8	2	4	15	38	42
2.0+	11.7	1	6	17	37	39
MEAN Kt/V						
≥ 1.2	11.7	2	6	17	37	39
< 1.2	11.4	5	11	21	30	33
MEAN SERUM ALBUMIN						
≥ 3.5/3.2 BCG/BCP [^]	11.8	1	4	16	37	41
< 3.5/3.2 BCG/BCP	11.1	7	15	23	30	25
ACCESS TYPE						
AV Fistula	11.8	2	5	15	37	42
AV Graft	11.7	1	5	18	37	39
Catheter	11.3	5	11	20	31	33

* Value suppressed because n ≤ 10.

[^] BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

Note: Percentages may not add up to 100% due to rounding.

The percent of patients with mean hemoglobin < 9 gm/dL was 2%. The percent of patients with mean hemoglobin < 10 gm/dL was 9%. The prevalence of patients with mean hemoglobin < 10 gm/dL was higher in females compared to males, in patients dialyzing less than 6 months compared to those dialyzing 6 months or longer, higher in patients 18-44 years of age compared to older patients, in patients with diabetes mellitus as the cause of ESRD compared to other causes of ESRD, and, as reported previously, higher in Blacks than in Whites (26).

A higher proportion of patients with a mean Kt/V < 1.2 compared to patients with higher mean Kt/V values had a mean hemoglobin value < 10 gm/dL. A higher proportion of patients dialyzed with a catheter had a mean hemoglobin < 10 gm/dL compared to patients dialyzed with either an AV fistula or an AV graft. A higher proportion of patients with a mean serum albumin < 3.5/3.2 (BCG/BCP) gm/dL compared to patients with higher mean serum albumin values had a mean hemoglobin < 10 gm/dL (TABLE 13). The prevalence of patients with mean hemoglobin < 10 gm/dL ranged from 6% to 11% among Networks (FIGURE 35).

Figure 35: Percent of adult in-center hemodialysis patients with mean hemoglobin < 10gm/dL, by Network, October–December 2000. 2001 ESRD CPM Project.

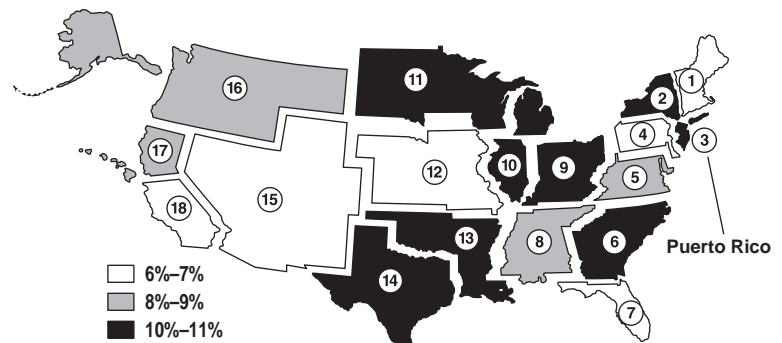


Table 14 shows, by Network, gender, race, ethnicity, and age group, the percent of patients prescribed Epoetin with hemoglobin values 11–12.9 gm/dL. The percent of all patients prescribed Epoetin with mean hemoglobin 11–12.9 gm/dL was 64% nationally and ranged from 59% to 69% by Network (TABLE 14). The percent of all patients prescribed Epoetin, with mean hemoglobin 11–12.9 gm/dL by race and age group, is shown in Figure 36. The percent of all patients with mean hemoglobin ≥ 11 gm/dL was 74% nationally and ranged from 69% to 78% by Network (FIGURES 37, 38).

TABLE 14: Percent of adult in-center hemodialysis patients prescribed Epoetin with mean hemoglobin 11-12.9 gm/dL, by gender, race, ethnicity, age, and Network, October-December 2000. 2001 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	65	66	63	69	60	65	67	66	61	64	61	64	59	65	63	65	66	65	64
GENDER																			
Men	68	65	65	70	60	64	67	67	65	62	59	65	59	63	65	64	67	67	65
Women	62	67	61	68	59	65	68	66	56	66	63	63	58	67	60	66	64	64	64
RACE																			
Black	68	63	65	73	58	64	64	68	62	66	55	64	58	63	70	74	70	63	64
White	64	70	65	68	60	64	71	65	61	65	63	62	58	65	61	64	63	66	65
ETHNICITY																			
Hispanic	58	62	60	*	75	*	67	*	*	63	71	70	*	65	62	74	65	68	65
Non-Hispanic	66	66	64	71	59	65	67	66	62	65	60	64	56	64	63	63	67	63	64
AGE GROUP (years)																			
18-44	48	66	57	58	50	64	61	61	64	58	58	54	50	60	62	60	63	57	59
45-54	59	62	74	73	64	63	71	75	62	70	55	61	65	67	70	61	71	67	66
55-64	69	63	66	70	49	64	61	64	55	68	65	71	60	71	62	67	57	68	64
65-74	66	65	59	71	66	61	69	64	59	60	58	55	61	64	58	64	66	60	63
75+	74	72	61	71	67	75	71	69	68	64	67	75	56	60	63	70	70	74	69

*Value suppressed because n ≤ 10.

Figure 36: *Percent of adult in-center hemodialysis patients prescribed Epoetin with mean hemoglobin 11–12.9 gm/dL, by age and race, October–December 2000. 2001 ESRD CPM Project.*

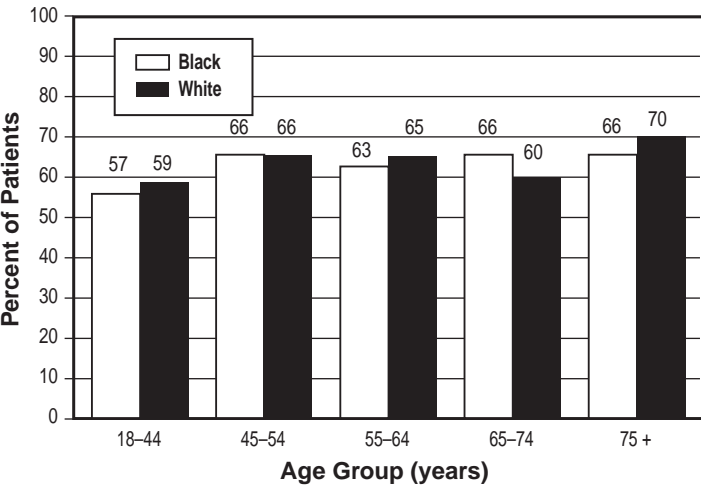


Figure 37: *Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by Network, October–December 2000. 2001 ESRD CPM Project.*

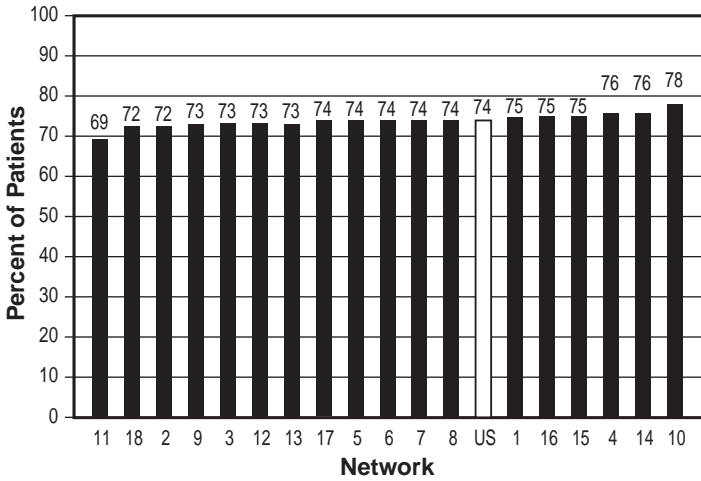
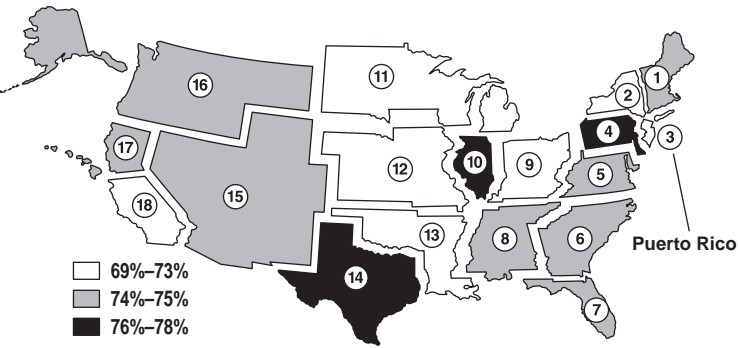


Figure 38: *Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by Network, October–December 2000. 2001 ESRD CPM Project.*



During this study period, data were collected on additional measures useful for anemia management (TABLE 15).

The national average (\pm SD) transferrin saturation for the patients in the sample was 28.6% (\pm 12.9%) and ranged from 26.9% to 30.3% among the 18 Network areas (TABLE 15). Table 15 also provides the percent of patients with mean transferrin saturation \geq 20% nationally (77%) and by Network area, ranging from 72% to 83%.

The national average (\pm SD) serum ferritin concentration for the patients in the sample was 529 ng/mL (\pm 394 ng/mL) and ranged from 463 to 618 ng/mL among the 18 Network areas. The percent of patients with a mean serum ferritin concentration \geq 100 ng/mL nationally was 89%, ranging from 84% to 92% among the 18 Network areas (TABLE 15).

69% of patients were prescribed either intravenous (IV) or oral iron at least once during the three-month study period. The percent of patients with IV iron prescribed nationally was 64%, ranging from 52% to 72% among the 18 Network areas (TABLE 15).

For the subset of patients with both mean transferrin saturation $<$ 20% and mean serum ferritin concentration $<$ 100 ng/mL ($n=365$ or 4% of patients), only 63% were prescribed IV iron at least once during the three-month study period.

Of the patients prescribed Epoetin, 91% were prescribed Epoetin by the IV route; and 11% by the SC route (groups not mutually exclusive). Prescribed SC administration, the route recommended by the NKF-DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure (4), ranged from 3% to 23% among the 18 Network areas (TABLE 15). The mean (\pm SD) Epoetin dose for patients prescribed Epoetin by the IV route was 82.6 units/kg/dose (\pm 70.4 units/kg/dose); by the SC route was 68.1 units/kg/dose (\pm 53.1 units/kg/dose).

TABLE 15: Regional variation for various anemia management measures for adult in-center hemodialysis patients including the percent of patients with mean hemoglobin ≥ 11 gm/dL, mean hemoglobin (gm/dL), and mean serum albumin ≥ 4.0 gm/dL[^], for these patients nationally and by Network, October-December 2000. 2001 ESRD CPM Project.

ANEMIA MANAGEMENT MEASURE:	NETWORK																		US
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
Percent of patients with mean hemoglobin ≥ 11 gm/dL	75	72	73	76	74	74	74	74	73	78	69	73	73	76	75	75	74	72	74
Mean hemoglobin (gm/dL)	11.7	11.6	11.6	11.6	11.7	11.6	11.6	11.6	11.6	11.7	11.5	11.6	11.7	11.7	11.8	11.7	11.6	11.6	11.6
Percent of patients with mean serum albumin ≥ 4.0 gm/dL [^]	23	30	30	28	29	26	25	25	23	33	24	25	28	28	27	24	27	30	27
Average transferrin saturation (TSAT) (%)	27.2	29.1	28.8	28.1	29.2	30.2	29.9	28.3	28.6	30.3	27.5	27.3	26.9	28.2	27.7	27.1	27.6	30.0	28.6
Percent of patients with mean TSAT $\geq 20\%$	73	78	75	78	80	83	82	77	73	82	76	74	72	76	77	73	74	80	77
Average serum ferritin concentration (ng/mL)	463	472	498	501	497	568	618	534	544	558	482	511	526	540	478	495	554	597	529
Percent of patients with mean serum ferritin concentration ≥ 100 ng/mL	84	87	86	86	87	92	90	91	91	92	90	88	90	92	90	88	91	91	89
Percent of patients with IV iron prescribed	62	60	62	65	52	66	62	63	72	69	64	63	71	64	63	69	59	59	64
Percent of patients * with subcutaneous Epoetin prescribed	5	4	5	6	3	4	4	5	23	18	17	18	7	12	5	21	14	21	11
Percent of patients with mean hemoglobin <11 gm/dL with Epoetin prescribed	96	98	95	96	99	97	96	94	96	96	97	98	97	97	97	98	96	94	96

[^]For subset of patients with serum albumin tested by the bromcresol green (BCG) laboratory method

*Among patients prescribed Epoetin

Table 16 depicts the odds ratio (95% CI) for experiencing a mean hemoglobin < 11 gm/dL by several patient and clinical characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example, a female has a 1.2 (or 20%) greater chance of experiencing a mean hemoglobin < 11 gm/dL than a male (without controlling for any other variables).

TABLE 16: Independent logistic regression analyses by selected patient and clinical characteristics to predict odds ratio (95% CI) for mean hemoglobin < 11 gm/dL, 2001 ESRD CPM Project.

Characteristic	Odds Ratio (95% CI)
GENDER	
Female	1.2 (1.1, 1.4)
Male (referent)	
RACE	
Black	1.1 (0.96, 1.2)
White (referent)	
ETHNICITY	
Hispanic	0.89 (0.77, 1.04)
Non-Hispanic (referent)	
AGE GROUP (years)	
18-44	1.3 (1.2, 1.5)
45+ (referent)	
DIABETES MELLITUS	
Yes	1.2 (1.1, 1.3)
No (referent)	
DURATION OF DIALYSIS (years)	
< 0.5	3.1 (2.7, 3.5)
≥ 0.5 years (referent)	
MEAN Kt/V	
< 1.2	1.9 (1.6, 2.1)
≥ 1.2 (referent)	
MEAN SERUM ALBUMIN	
< 3.5/ < 3.2 gm/dL (BCG/BCP)*	2.9 (2.6, 3.2)
≥ 3.5/ ≥ 3.2 gm/dL (BCG/BCP) (referent)	
EPOETIN	
prescribed during study period	1.4 (1.1, 1.8)
not prescribed (referent)	
MEAN TRANSFERRIN SATURATION	
< 20%	2.4 (2.1, 2.7)
≥ 20% (referent)	
MEAN SERUM FERRITIN CONCENTRATION	
< 100 ng/mL	1.3, (1.1, 1.5)
≥ 100 ng/mL (referent)	
VASCULAR ACCESS	
AV Graft	1.1 (1.0, 1.3)
Catheter	2.1 (1.8, 2.4)
(AV Fistula = referent)	

* BCG = bromocresol green laboratory method;
BCP = bromocresol purple laboratory method

3. CPM and Other Findings for October-December 2000 compared to previous study periods

NOTE: The following findings apply to all the adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The average hemoglobin (± SD) from October–December 1999 to October–December 2000 increased from 11.4 gm/dL (± 1.3) to 11.6 gm/dL (± 1.2) (FIGURE 9), and the percent of patients with a mean hemoglobin ≥ 11 gm/dL increased significantly from 68% to 74% (FIGURES 8, 9, 39).

In addition to the improvement in the percent of patients with mean hemoglobin ≥ 11 gm/dL, there was also a decrease in the percent of patients with mean hemoglobin < 10 gm/dL. In October–December 1999, 15% of Black patients and 10% of White patients had a mean hemoglobin < 10 gm/dL, while in October–December 2000, 10% of Black patients and 8% of White patients had a mean hemoglobin < 10 gm/dL.

The percent of patients prescribed Epoetin by hemoglobin category in late 1997, 1998, 1999, and 2000, is shown in Figure 40. Figure 41 depicts the trend for increasing Epoetin dosing (units/kg/dose) from late 1997 to late 2000. SC Epoetin doses were systematically lower than IV Epoetin doses at all hemoglobin categories examined. 11% of patients were prescribed SC Epoetin in late 2000, a slight change from late 1999 (FIGURE 42).

Figure 42 depicts the status of iron stores for the sampled patients in late 2000 compared to previous study periods. Overall, 64% of patients were prescribed IV iron in late 2000 compared to 51% in late 1996. Within the subgroup of patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 63% of patients were prescribed IV iron at least once over the three-month study period in late 2000, compared to 37% in late 1996.

Figure 39: Percent of adult in-center hemodialysis patients with mean hemoglobin values ≥ 11 gm/dL, by race, October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.

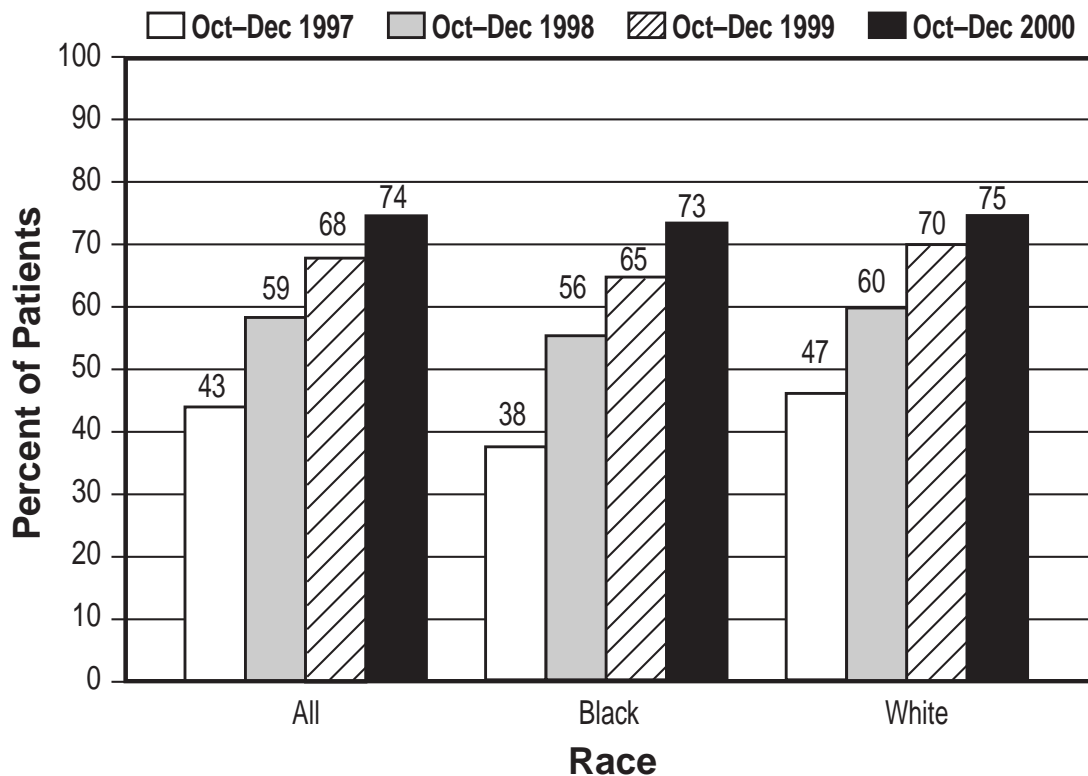


Figure 40: Percent of adult in-center hemodialysis patients who were prescribed Epoetin by hemoglobin category, October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.

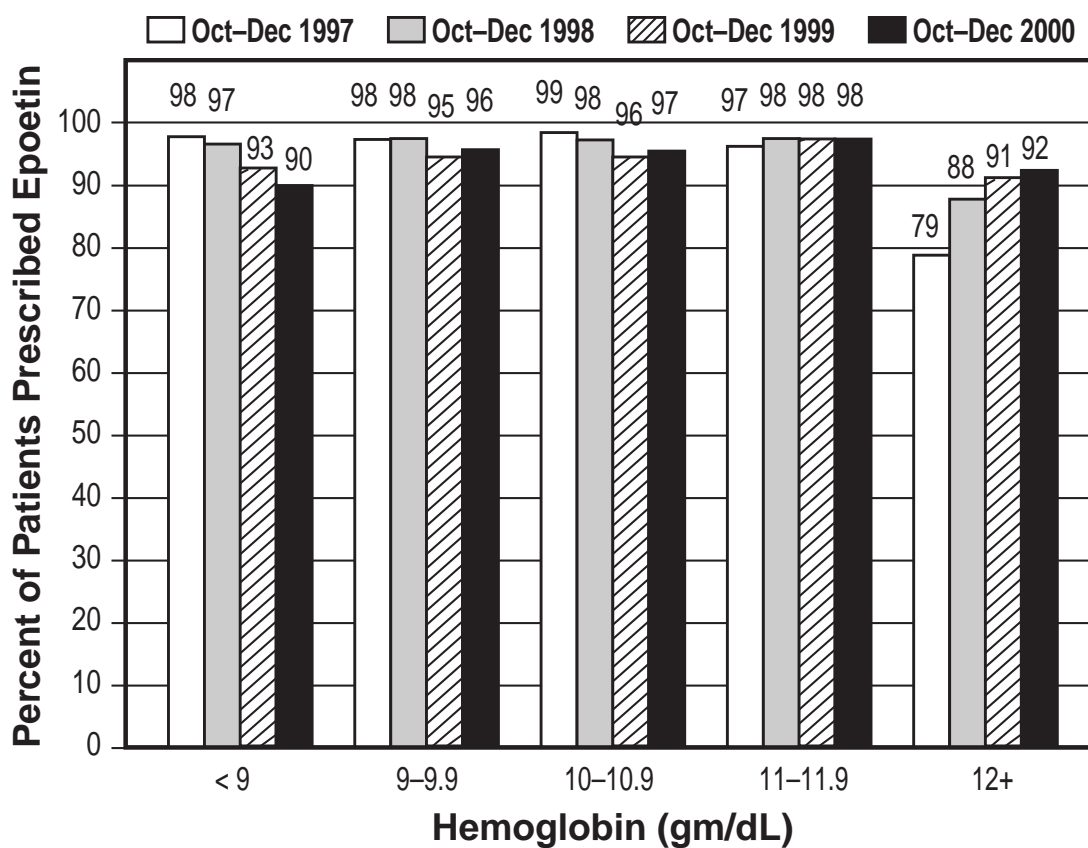


Figure 41: Mean prescribed Epoetin dose (units/kg/dose) for adult in-center hemodialysis patients, by hemoglobin category and route of administration, October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.

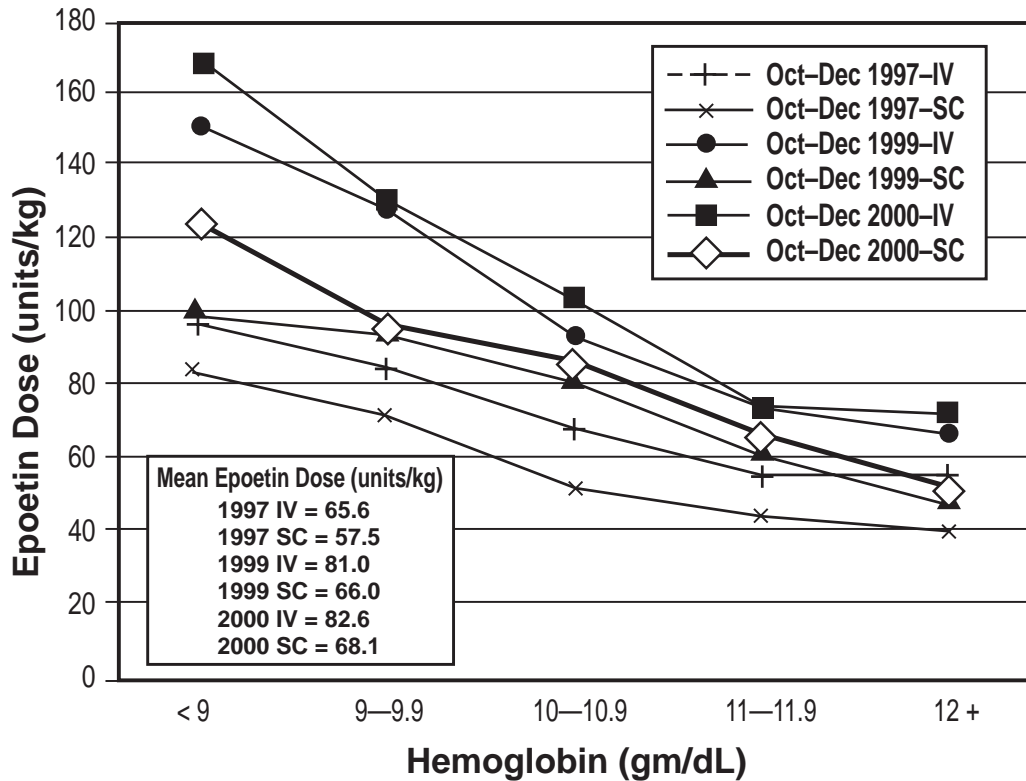
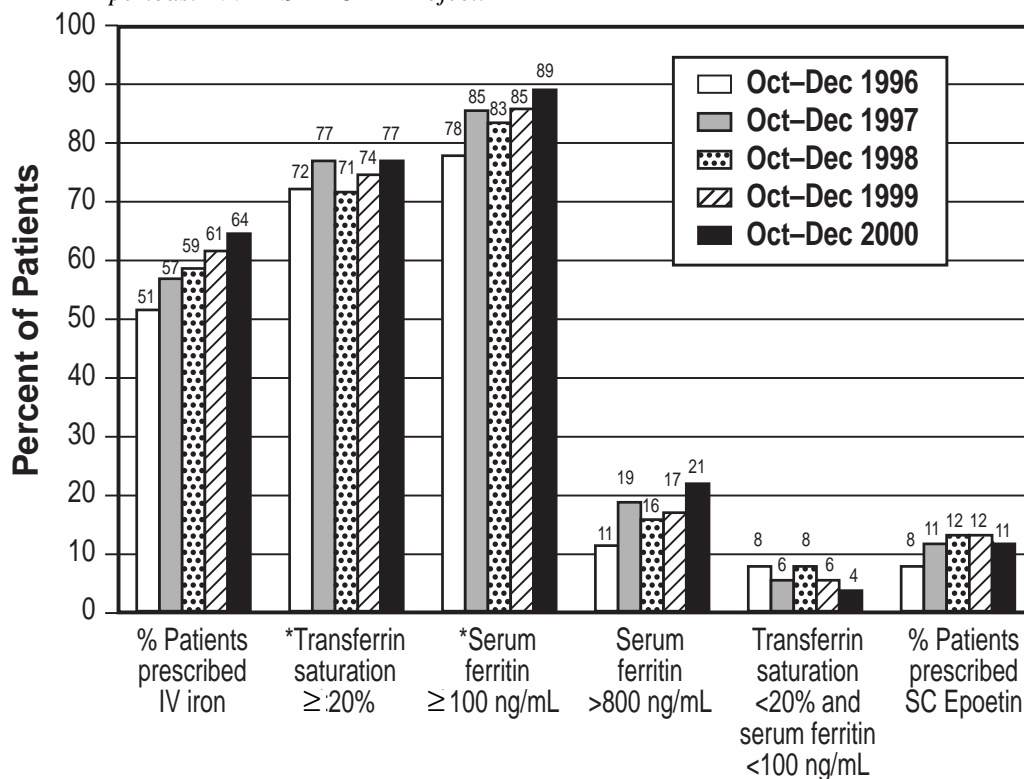


Figure 42: Percent of adult in-center hemodialysis patients with specific anemia management indicators, October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.



*In previous Annual Reports, the denominator was the entire sample. In this Annual Report, the denominator was the subset of patients with at least one reported measure during the study period.

D. SERUM ALBUMIN

1. Findings for October–December 2000

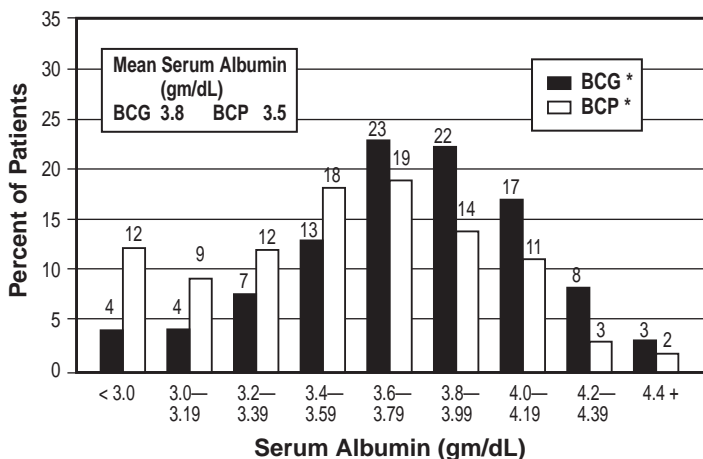
The two commonly used laboratory methods for determining serum albumin values, bromocresol green (BCG) and bromocresol purple (BCP), have been reported to yield systematically different results (20). Therefore, we assessed the serum albumin values reported for these two methods separately. As expected, the values determined by the BCP method were systematically lower than those determined by the BCG method.

The mean (\pm SD) serum albumin value for patients whose value was determined by the BCG method ($n=7231$) was 3.8 gm/dL (± 0.4 gm/dL), and by the BCP method ($n=1129$) was 3.5 gm/dL (± 0.5 gm/dL).

Mean serum albumin < 3.5 gm/dL by the BCG method has been shown to be a marker for diminished survival (27-29). Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was nearly the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we also defined a mean BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. "Optimal" serum albumin was defined as ≥ 4.0 gm/dL by the BCG method or ≥ 3.7 gm/dL by the BCP method. Figure 43 displays the distribution of serum albumin values by laboratory method.

The percents of patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) and $\geq 3.5/3.2$ gm/dL (BCG/BCP) by gender, race, ethnicity, age, diagnosis groups, duration of dialysis, and selected clinical parameters are shown in Table 17. A higher percent of men, Blacks, Hispanics, patients 18-44 years old, patients with causes of ESRD other than diabetes mellitus, and patients dialyzing six months or longer had a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) compared to women, Whites, non-Hispanics, patients older than 44 years, patients with diabetes mellitus as the cause of ESRD, and patients dialyzing less than six months (TABLE 17).

Figure 43: Distribution of mean serum albumin for adult in-center hemodialysis patients, by laboratory method, October–December 2000. 2001 ESRD CPM Project.



* Note: BCG = bromocresol green laboratory method
BCP = bromocresol purple laboratory method

A higher percent of patients with a mean hemoglobin ≥ 11 gm/dL, had a mean serum albumin $\geq 4.0/3.7$ gm/dL. (BCG/BCP) compared to patients with lower mean hemoglobin values (32% vs. 19%, respectively). More patients dialyzed with either an AV fistula or an AV graft compared to patients dialyzed with a catheter had a mean serum albumin $\geq 4.0/3.7$ gm/dL. (BCG/BCP) (37% and 29% vs. 18% respectively) (TABLE 17).

TABLE 17: Percent of adult in-center hemodialysis patients with mean serum albumin values $\geq 4.0/3.7$ gm/dL (BCG/BCP)* and $\geq 3.5/3.2$ gm/dL (BCG/BCP) in the US, by patient characteristics, October-December 2000. 2001 ESRD CPM Project.

Patient Characteristic	Percent of Patients with Mean Serum Albumin $\geq 4.0/3.7$ gm/dL	$\geq 3.5/3.2$ gm/dL
TOTAL	29	80
GENDER		
Men	35	83
Women	22	77
RACE		
American Indian/Alaska Native	12	65
Asian/Pacific Islander	34	83
Black	31	82
White	27	78
Other/Unknown	33	82
ETHNICITY		
Hispanic	33	81
Non-Hispanic	28	80
AGE GROUP (years)		
18-44	43	84
45-54	33	81
55-64	30	80
65-74	23	79
75+	20	76
DIAGNOSIS		
Diabetes mellitus	21	76
Hypertension	34	83
Glomerulonephritis	39	87
Other/Unknown	32	80
DURATION of DIALYSIS (years)		
< 0.5	13	58
0.5-0.9	22	74
1.0-1.9	31	84
2.0+	33	85
MEAN Kt/V ≥ 1.2	29	81
< 1.2	28	74
MEAN Hgb ≥ 11 gm/dL	32	85
< 11 gm/dL	19	66
ACCESS TYPE		
AV Fistula	37	86
AF Graft	29	83
Catheter	18	66

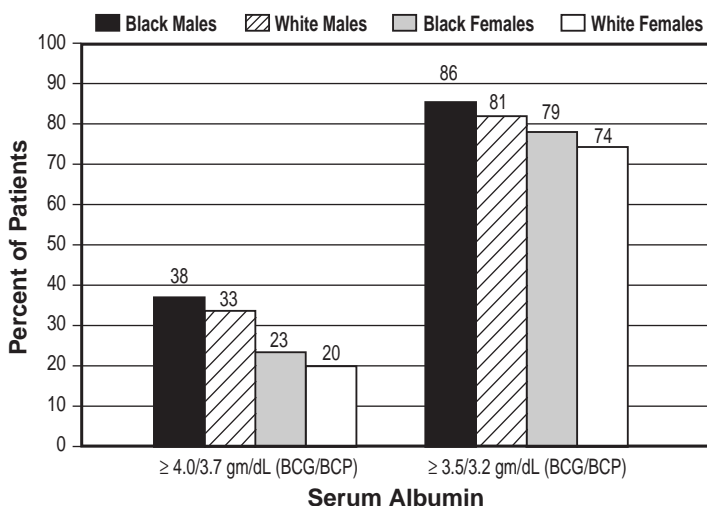
* Note: BCG = bromocresol green laboratory method
BCP = bromocresol purple laboratory method

Nationally, 29% of patients had mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) ranging from 23% to 34% among the 18 Networks; 80% of patients had mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP) ranging from 74% to 83% among the 18 Networks. The percent of patients in each Network area, by gender, race, ethnicity, and age group, with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) is shown in Table 18.

The percent of patients achieving on average either an “adequate” or an “optimal” serum albumin over the three month study period tended to be higher for men compared to women, for Black patients compared to White patients, and for patients 18-44 years old compared to older patients (FIGURE 44, TABLES 17 and 18).

A higher percentage of patients with causes of ESRD other than diabetes mellitus achieved on average an “optimal” serum albumin over the three month study period compared to patients with diabetes mellitus as the cause of ESRD patients (34% vs. 21% respectively). Only 13% of patients dialyzing less than six months achieved an “optimal” serum albumin compared to 33% of patients dialyzing two or more years.

Figure 44: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)* and $\geq 3.5/3.2$ gm/dL (BCG/BCP), by race and gender, October–December 2000. 2001 ESRD CPM Project.



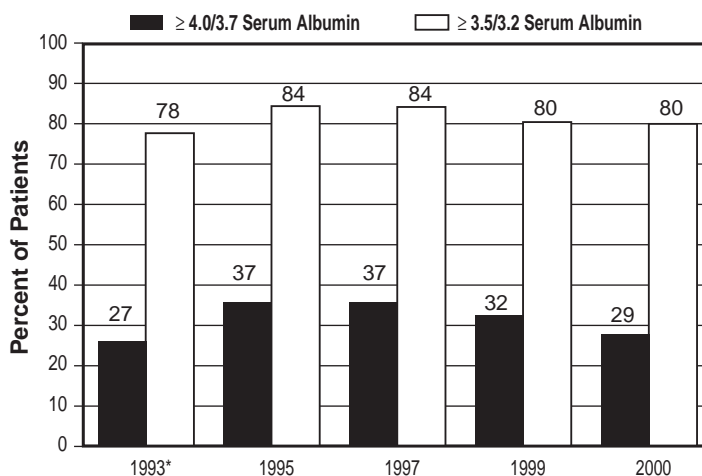
*Note: BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

2. Findings for October–December 2000 compared to previous study periods

No clinically important changes or improvements were noted in the proportion of adult in-center hemodialysis patients with “adequate” or “optimal” serum albumin levels during October–December 2000 compared to previous study periods.

Figure 45 shows the percent of patients with mean serum albumin ≥ 4.0 gm/dL (BCG) or ≥ 3.7 gm/dL (BCP) and the percent of patients with mean serum albumin values ≥ 3.5 gm/dL (BCG) or ≥ 3.2 gm/dL (BCP) during October–December 2000 compared to previous study periods.

Figure 45: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)** and $\geq 3.5/3.2$ gm/dL (BCG/BCP), October–December 2000 compared to previous study periods. 2001 ESRD CPM Project.



* Sixteen Network areas participated in the first ESRD Core Indicators Project assessment (October–December 1993); all Network areas participated in subsequent years.

** Note: BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

TABLE 18: Percent of adult in-center hemodialysis patients with mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method), by gender, race, ethnicity, age, and Network, October-December 2000. 2001 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	27	31	30	28	32	27	28	28	25	34	25	27	34	29	27	23	28	32	29
GENDER																			
Men	31	32	32	35	42	36	34	36	29	43	30	30	45	38	36	29	33	42	35
Women	22	30	26	21	22	19	21	22	20	26	20	23	22	20	18	16	22	23	22
RACE																			
Black	28	39	28	29	37	28	29	30	26	35	28	33	35	24	32	*	27	33	31
White	25	21	30	28	23	27	27	27	24	34	24	21	32	31	30	24	28	30	27
ETHNICITY																			
Hispanic	*	40	34	*	*	*	37	*	*	30	*	*	*	36	30	30	33	29	33
Non-Hispanic	27	29	28	29	32	27	27	28	25	35	26	27	34	23	26	23	27	34	28
AGE GROUP (years)																			
18-44	48	51	49	44	46	43	37	40	39	51	32	31	40	40	41	49	37	51	43
45-54	27	46	31	32	29	28	35	26	26	36	32	29	35	32	33	25	37	46	33
55-64	28	33	28	28	32	25	29	29	25	31	28	24	41	29	27	21	30	35	30
65-74	26	15	26	27	29	21	25	27	20	34	19	29	23	28	20	15	21	20	23
75+	17	16	22	20	26	22	22	22	20	26	19	22	29	*	21	12	21	18	20

* Value suppressed because $n \leq 10$.

PERITONEAL DIALYSIS PATIENTS

SYNOPSIS

• **Purpose of Project:** The ultimate purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in improving the care provided to ESRD patients. The specific purposes of the 2001 project were:

To compare the prevalence of important clinical characteristics of adult (aged ≥ 18 years) peritoneal dialysis patients in the US in October 2000–March 2001 to the prevalence of those characteristics in November 1994–April 1995; November 1995–April 1996; November 1996–April 1997; November 1997–April 1998; October 1998–March 1999; and October 1999–March 2000;

AND, to identify opportunities to improve care for those patients.

• **Method Used:** A national random sample of adult peritoneal dialysis patients who were alive on December 31, 2000, was selected (sample size 1,439).

ESRD facilities with one or more patients in the sample submitted completed data collection forms to their respective ESRD Network. The Networks then submitted a data file to ESRD Network 9/10 with the clinical information about these patients for the time period October 2000–March 2001 for aggregation. This aggregated data file was then forwarded to CMS for initial analysis.

• **Initial Findings:** The sample for analysis consisted of 1,342 patients, which was 93% of the original sample. Highlights from the initial findings are summarized below.

IMPROVEMENT OCCURRED

• Adequacy of dialysis was assessed at least once for 85% of the sampled patients during the 2001 study period (October 2000–March 2001), compared to 83% during the 2000 study period (October 1999–March 2000) and 82% during the 1999 study period (November 1998–April 1999) (FIGURE 7).

• 67% of CAPD patients had a mean weekly Kt/V_{urea} meeting NKF-DOQI guidelines (3) during the 2001 study period compared to 65% during the 2000 study period. 61% of

CAPD patients had a mean weekly creatinine clearance (CrCl) meeting these guidelines during the 2001 study period, no improvement from the 2000 study period. (FIGURES 5, 6, TABLE 19).

• 58% of cycler patients had a mean weekly Kt/V_{urea} and 52% had a mean weekly CrCl that met NKF-DOQI guidelines (3) during the 2001 study period. This compares to 60% and 51% during the 2000 study period, respectively (Table 19).

• An improvement of 4 percentage points occurred in the percent of peritoneal dialysis patients with mean hemoglobin ≥ 11 gm/dL from the 2000 study period (69%) to the 2001 study period (73%) (FIGURE 10).

OPPORTUNITIES TO IMPROVE

• The adequacy of dialysis was not assessed during the 2001 study period for 15% of the sampled peritoneal dialysis patients.

• 33% of CAPD patients did not achieve an adequate weekly Kt/V_{urea} and 39% did not meet an adequate weekly CrCl. Likewise, 42% of cycler patients did not achieve an adequate weekly Kt/V_{urea} and 48% did not achieve an adequate weekly CrCl.

• 27% of patients did not have a mean hemoglobin ≥ 11 gm/dL in the 2001 study period.

• 61% of peritoneal dialysis patients who met the inclusion criteria and were prescribed Epoetin did not have a mean hemoglobin 11–12.0 gm/dL in the 2001 study period.

• 86% of peritoneal dialysis patients did not have mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method) in the 2001 study period.

• 44% of peritoneal dialysis patients did not have mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method) in the 2001 study period.

NEXT STEPS:

Network and CMS staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2002, 2003 and beyond.

Using the 1997 NKF-DOQI guidelines (3):

For CAPD patients: weekly $Kt/V_{urea} \geq 2.0$; weekly CrCl ≥ 60 L/week/1.73m²

For cycler patients with daytime dwell (CCPD patients): weekly $Kt/V_{urea} \geq 2.1$; weekly CrCl ≥ 63 L/week/1.73m²

For nighttime cycler patients (NIPD patients) (no daytime dwell): weekly $Kt/V_{urea} \geq 2.2$; weekly CrCl ≥ 66 L/week/1.73m²

This report does not reflect the revised 2001 guidelines or proposed guideline revisions.

IV. ADULT PERITONEAL DIALYSIS PATIENTS

This section describes the findings for adult peritoneal dialysis patients for selected CPMs and other quality indicators related to adequacy of peritoneal dialysis, anemia management, and serum albumin. Each of these sections is further broken down into three parts: (1) national findings for selected CPM results for October 2000–March 2001 (the serum albumin information is not considered a CPM for this report); (2) a description of other quality indicators or data analysis; and (3) a comparison of CPM and/or other indicators or findings for October 2000–March 2001 and previous study periods. A national random sample of adult (≥ 18 years) peritoneal dialysis patients who were alive on December 31, 2000, was selected (sample size=1439). 1342 patients (93%) were included in the sample for analysis.

A. ADEQUACY OF PERITONEAL DIALYSIS

1. CPM Findings for October 2000–March 2001

Data to assess three peritoneal dialysis adequacy CPMs were collected in 2001. The time period from which these data were abstracted was October 2000–March 2001. Tidal peritoneal dialysis patients ($n=43$) were excluded from the peritoneal dialysis adequacy CPM calculations.

Peritoneal Dialysis Adequacy CPM I — The patient's total solute clearance for urea and creatinine is measured routinely (defined for this report as at least once during the six-month study period).

FINDING: 85% of adult peritoneal dialysis patients had both a weekly Kt/V_{urea} and a weekly creatinine clearance measurement reported at least once during the six-month study period.

Peritoneal Dialysis Adequacy CPM II — The patient's total solute clearance for urea (weekly Kt/V_{urea}) and creatinine (weekly creatinine clearance) is calculated in a standard way. (See Peritoneal Dialysis Adequacy CPM II in Appendix 1).

FINDING: 62% of adult peritoneal dialysis patients who had reported adequacy measurements documented in their chart at least once during the six-month study period had these reported measurements calculated (Kt/V_{urea} and creatinine clearance) in a standard way as described in Peritoneal Dialysis Adequacy CPM II in Appendix 1.

Peritoneal Dialysis Adequacy CPM III — For patients on CAPD, the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.0 and a weekly creatinine clearance of at least 60 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For CCPD patients (cycler patients with a daytime dwell), the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.1 and a weekly creatinine clearance of at least 63 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For NIPD patients (cycler patients without a daytime dwell), the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.2 and a weekly creatinine clearance of at least 66 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

FINDING: 69% of CAPD patients had a mean weekly $Kt/V_{urea} \geq 2.0$ and a mean weekly creatinine clearance ≥ 60 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

ALTERNATE FINDING: 67% (231/346) of CAPD patients with a PET result within 12 months of or during the study period met the revised K/DOQI thresholds for peritoneal dialysis adequacy (30) (a mean weekly $Kt/V_{urea} \geq 2.0$ and for high and high-average transporters, a weekly creatinine clearance ≥ 60 L/week/1.73 m², for low and low-average transporters, a weekly creatinine clearance ≥ 50 L/week/1.73 m², OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period).

FINDING: 62% of cycler patients with a daytime dwell (CCPD patients) had a mean weekly $Kt/V_{urea} \geq 2.1$ and a mean weekly creatinine clearance ≥ 63 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

FINDING: 64% of cycler patients without a daytime dwell (NIPD patients) had a mean weekly $Kt/V_{urea} \geq 2.2$ and a mean weekly creatinine clearance ≥ 66 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

2. Other Peritoneal Dialysis Adequacy Findings for October 2000–March 2001

Tidal peritoneal dialysis patients ($n=43$) were excluded from the peritoneal dialysis adequacy analyses reported below. By using values that were abstracted from medical records of peritoneal dialysis patients, it was possible to calculate at least one of the adequacy measures (weekly Kt/V_{urea} or weekly creatinine clearance) for 1,071 (82%) of the 1,299 patients included for these analyses during the 2001 study period.

67% of CAPD and 58% of cycler patients had a mean calculated weekly Kt/V_{urea} that met recommended NKF DOQI guidelines; 61% of CAPD and 52% of cycler patients had a mean calculated weekly creatinine clearance that met recommended NKF-DOQI guidelines (TABLE 19).

41% of patients ($n=535$) had one or more Peritoneal Equilibration Test (PET) results within 12 months of or during the study period. The distribution of PET results is depicted in Figure 46.

32% of CAPD patients had a total prescription volume of 8000 mL and 30% had a total prescription volume of 10,000 mL (FIGURE 47).

33% of allycler patients had a single nighttime dwell volume of 2500 mL; 27% had a single nighttime dwell volume of 2000 mL (FIGURE 48). 41% of allycler patients had a mean of four nighttime exchanges, 25% had a mean of 5 nighttime exchanges, and another 14% had a mean of 3 nighttime exchanges (FIGURE 49).

10% (n = 67) ofycler patients did not have a daytime dwell. 41% ofycler patients with a daytime dwell had a mean single daytime dwell volume of 2000 mL; 20% had a mean single daytime dwell volume of 2500 mL (FIGURE 50). 50% of these patients had one daytime exchange, another 39% had two daytime exchanges (FIGURE 51).

Figure 46: Distribution of Peritoneal Equilibration Test (PET) results for adult peritoneal dialysis patients, October 2000-March 2001. 2001 ESRD CPM Project.

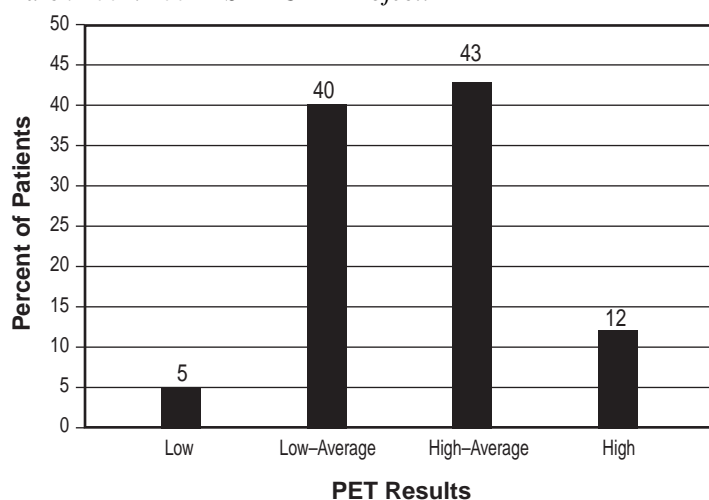


Figure 47: Distribution of single dwell volumes and 24-hour total infused dialysate volumes for adult CAPD patients, October 2000-March 2001. 2001 ESRD CPM Project.

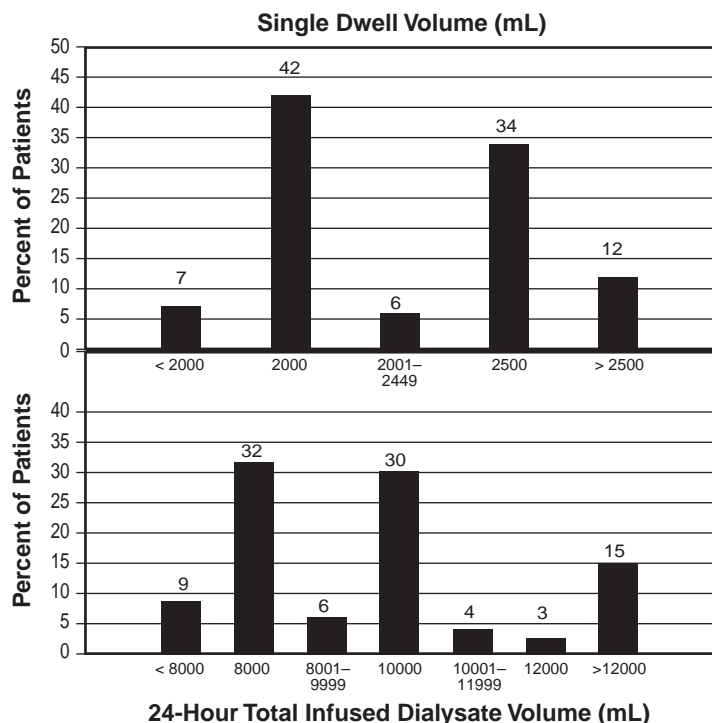


Figure 48: Distribution of mean single nighttime dwell volumes for all adultycler patients, October 2000-March 2001. 2001 ESRD CPM Project.

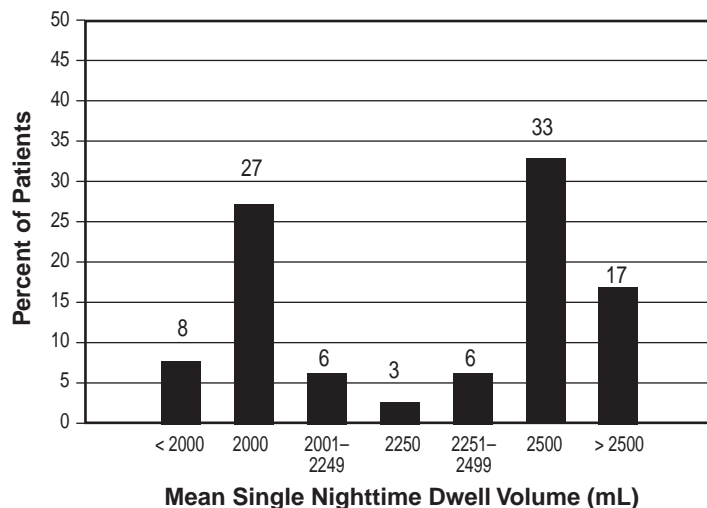


Figure 49: Distribution of the mean number of nighttime exchanges for all adultycler patients, October 2000-March 2001. 2001 ESRD CPM Project.

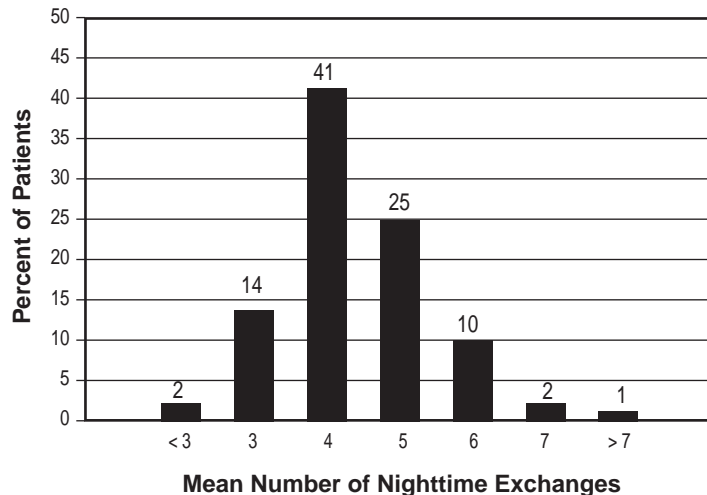


Figure 50: Distribution of mean single daytime dwell volumes for adultycler patients with a daytime dwell, October 2000-March 2001. 2001 ESRD CPM Project.

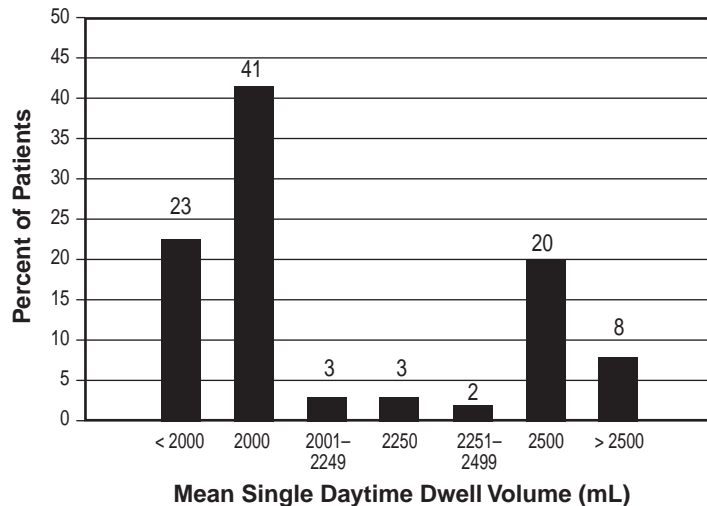
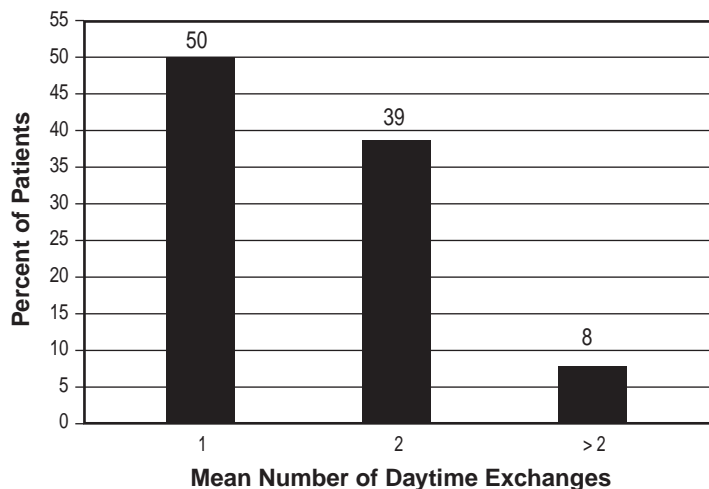


Figure 51: Distribution of the mean number of daytime exchanges for adult cycler patients with a daytime dwell, October 2000–March 2001. 2001 ESRD CPM Project.



3. CPM and Other Findings for October 2000–March 2001 compared to previous study periods

The adequacy of peritoneal dialysis was reported for 85% of adult peritoneal dialysis patients at least once during the 2001 six-month study period, October 2000–March 2001 (PD Adequacy CPM I), compared to only 82% during the 1999 study period, and 83% during the 2000 study period (FIGURE 7). There has been an increase in the standard measurement of total solute clearance for urea and creatinine reported by facility staff from 1999–2001 (PD Adequacy CPM II) (FIGURE 7).

In addition to increasing numbers of patients having an adequacy measurement performed during the six-month study period, both CAPD and cycler patients have experienced improved clearances from November 1995–April 1996 to October 2000–March 2001 (TABLE 19). Although the percent of patients meeting NKF-DOQI thresholds for peritoneal dialysis adequacy (3) has increased from the 1999 study period, there was little change in the percent of patients meeting these thresholds from the 2000 study period to the 2001 study period (FIGURE 52).

Figures 53 and 54 depict the improvement in the delivered adequacy of dialysis for cycler patients with a daytime dwell (CCPD patients) from the 1996–2001 study periods. Figures 55 and 56 depict the improvement in the delivered adequacy of dialysis for cycler patients without a daytime dwell (NIPD patients) from the 1996–2001 study periods. Mean weekly creatinine clearance values for all cycler patients increased over this time period (TABLE 19). A similar improvement in adequacy measures occurred for CAPD patients (FIGURES 5, 6, TABLE 19).

Figure 52: Percent of adult peritoneal dialysis patients meeting NKF-DOQI guidelines for weekly Kt/V_{urea} and weekly creatinine clearance (PD Adequacy CPM III). 2001 ESRD CPM Project.

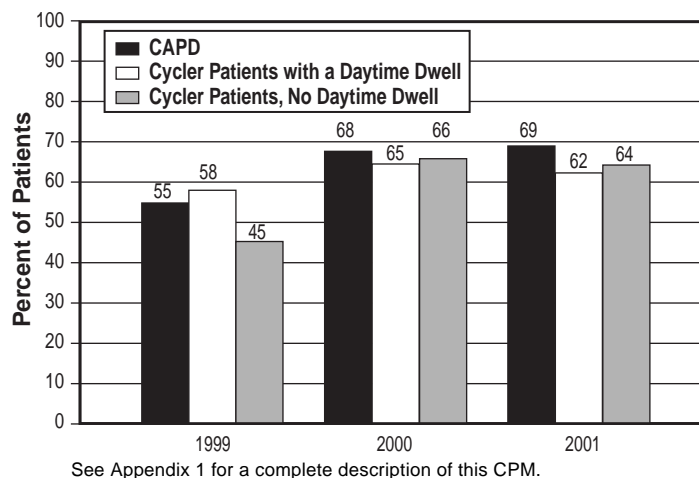


Figure 53: Distribution of mean weekly Kt/V_{urea} for adult cycler patients with a daytime dwell, October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.

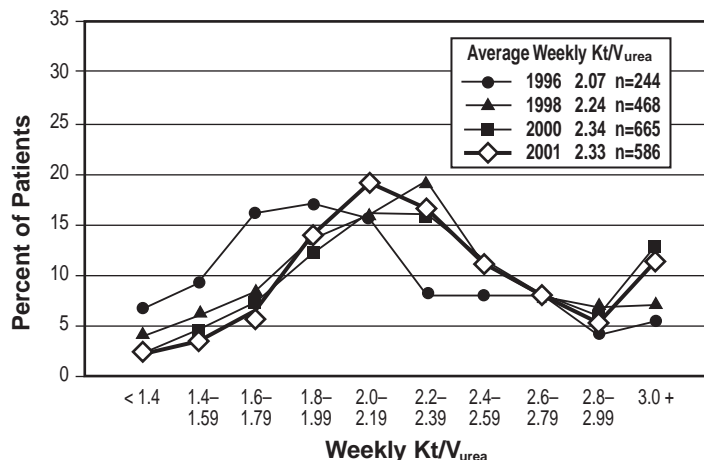


Figure 54: Distribution of mean weekly creatinine clearance ($L/week/1.73m^2$) for adult cycler patients with a daytime dwell, October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.

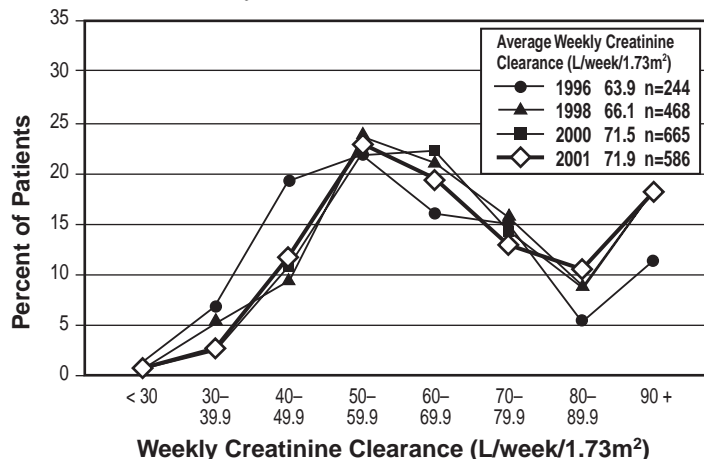


TABLE 19: Percent of adult peritoneal dialysis patients with mean (\pm SD) weekly adequacy values meeting NKF-DOQI guidelines, and median adequacy values, October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.

	Nov 95–Apr 96		Nov 97–Apr 98		Oct 98–Mar 99		Oct 99–Mar 00		Oct 00–Mar 01	
Adequacy Measure	CAPD (n=796)	Cyclers (n=402)	CAPD (n=804)	Cyclers (n=663)	CAPD (n=762)	Cyclers [†] (n=626)	CAPD (n=646)	Cyclers ^{††} (n=745)	CAPD (n=534)	Cyclers ^{†††} (n=653)
Weekly Kt/V urea										
% meeting NKF-DOQI [^]	27	28	45	42	56	52	65	60	67	58
mean (\pm SD)	2.00 (± 0.6)	2.12 (± 0.6)	2.20 (± 0.6)	2.25 (± 0.6)	2.22 (± 0.5)	2.31 (± 0.6)	2.27 (± 0.6)	2.34 (± 0.6)	2.31 (± 0.5)	2.33 (± 0.6)
median	1.90	2.00	2.10	2.20	2.20	2.30	2.20	2.20	2.23	2.24
Weekly Creatinine Clearance										
% meeting NKF-DOQI	30	26	41	32	51	43	61	51	61	52
mean (\pm SD)	64.3 (± 23.6)	63.4 (± 23.5)	67.8 (± 22.6)	66.5 (± 22.0)	70.4 (± 25.2)	69.1 (± 23.7)	72.7 (± 24.9)	71.6 (± 25.1)	74.8 (± 26.3)	72.4 (± 26.1)
median	59.6	59.0	63.0	60.8	64.9	63.6	65.9	65.5	69.4	65.9

[^] NKF-DOQI guidelines (3):

For CAPD patients: $Kt/V_{urea} \geq 2.0$; creatinine clearance ≥ 60 L/week/1.73m²

For cycler patients with daytime dwell (CCPD patients): $Kt/V_{urea} \geq 2.1$; creatinine clearance ≥ 63 L/week/1.73m²

For nighttime cycler patients (no daytime dwell) (NIPD patients): $Kt/V_{urea} \geq 2.2$; clearance ≥ 66 L/week/1.73m²

[†] Tidal peritoneal dialysis patients were excluded from these analyses (n = 53).

^{††} Tidal peritoneal dialysis patients were excluded from these analyses (n = 24).

^{†††} Tidal peritoneal dialysis patients were excluded from these analyses (n = 43).

Figure 55: Distribution of mean weekly Kt/V_{urea} for adult cycler patients without a daytime dwell, October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.

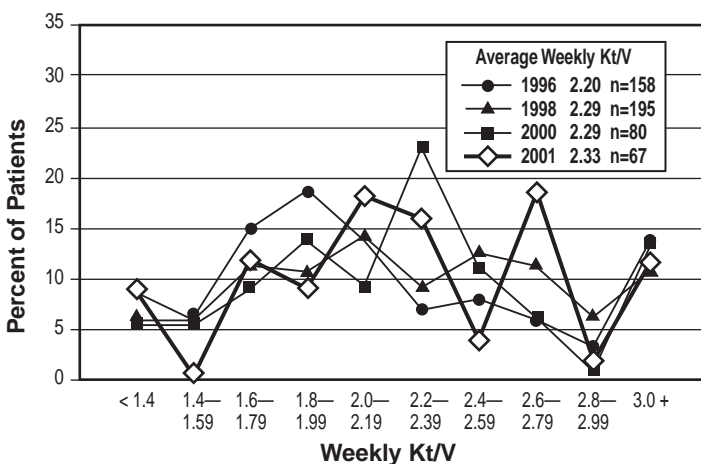
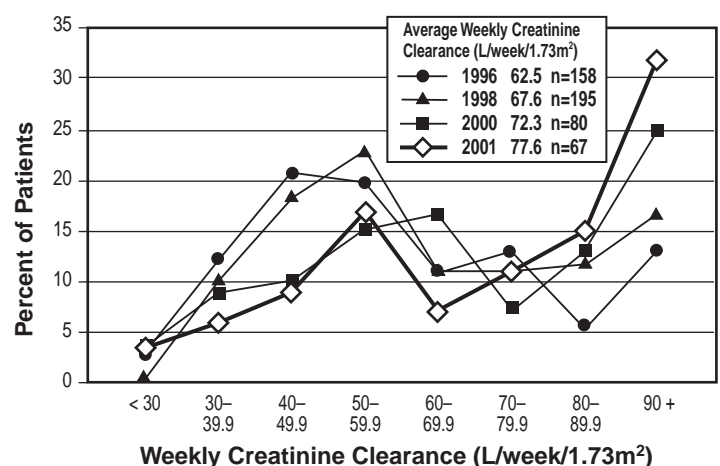


Figure 56: Distribution of mean weekly creatinine clearance (L/week/1.73m²) for adult cycler patients without a daytime dwell, October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.



B. ANEMIA MANAGEMENT

1. CPM Findings for October 2000–March 2001

Data to assess three anemia management CPMs were collected in 2001. The time period from which these data were abstracted was October 2000–March 2001.

Anemia Management CPM I — The target hemoglobin is 11–12 gm/dL. Patients with a mean hemoglobin > 12 gm/dL and not prescribed Epoetin were excluded from analysis for this CPM.

FINDING: For the six-month study period, 39% of the peritoneal dialysis patients who met the inclusion criteria (n=1214) had a mean hemoglobin 11–12.0 gm/dL.

Anemia Management CPM IIa — For all anemic patients (hemoglobin < 11 gm/dL) or patients prescribed Epoetin, the percent transferrin saturation and serum ferritin concentration are assessed (measured) at least two times during the six month study period.

FINDING: 72% of the peritoneal dialysis patients who met the inclusion criteria (n=1206) had at least two documented (measured) transferrin saturation values and at least two documented (measured) serum ferritin concentration values during October 2000–March 2001.

Anemia Management CPM IIb — For all anemic patients (hemoglobin < 11 gm/dL) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation ≥ 20% were documented during the six-month study period.

FINDING: 75% of the adult peritoneal dialysis patients who met the inclusion criteria (n=1206) had at least one documented transferrin saturation ≥ 20% and at least one documented serum ferritin concentration ≥ 100 ng/mL during October 2000–March 2001.

Anemia Management CPM III — All anemic patients (hemoglobin < 11 gm/dL) or patients prescribed Epoetin, with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was ≥ 50% or the mean serum ferritin concentration was ≥ 800 ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

FINDING: 23% of the peritoneal dialysis patients who met the inclusion criteria (n=517) were prescribed intravenous iron in at least one of the two-month periods during October 2000–March 2001.

2. Other Anemia Management Findings for October 2000–March 2001

The average (\pm SD) hemoglobin for adult peritoneal dialysis patients in the sample was 11.7 gm/dL (\pm 1.4 gm/dL). The distributions of mean hemoglobin values for Black and White patients are depicted in Figure 57. The mean hemoglobin values and the proportion of patients within different hemoglobin categories for gender, race, ethnicity, age, diagnosis, duration of dialysis, mean serum albumin level and weekly creatinine clearance are shown in Table 20. 73% of patients had a mean hemoglobin ≥ 11 gm/dL (FIGURE 10, TABLE 20). Significantly more men, Whites, and patients older than 45 years had a mean hemoglobin ≥ 11 gm/dL compared to women, Blacks, and younger patients (TABLE 20). More patients with a mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP) had a mean hemoglobin ≥ 11 gm/dL compared to patients with lower mean serum albumin values. Nationally, 61% of patients prescribed Epoetin had a mean hemoglobin 11–12.9 gm/dL.

The prevalence of patients with mean hemoglobin < 9 gm/dL was 3% (FIGURE 57, TABLE 20). The prevalence of patients with mean hemoglobin < 10 gm/dL was 9%. The prevalence of patients with mean hemoglobin < 10 gm/dL was significantly higher in women compared to men, Blacks compared to Whites, for patients 18–44 years old compared to older patients, in patients with mean serum albumin < 3.5/3.2 (BCG/BCP) compared to patients with higher mean serum albumin values, and in patients with mean weekly creatinine clearance < 60 L/week/1.73m² compared to patients with higher mean weekly creatinine clearance values (TABLE 20).

Figure 57: Distribution of mean hemoglobin values for adult peritoneal dialysis patients in the US, by race, October 2000–March 2001. 2001 ESRD CPM Project.

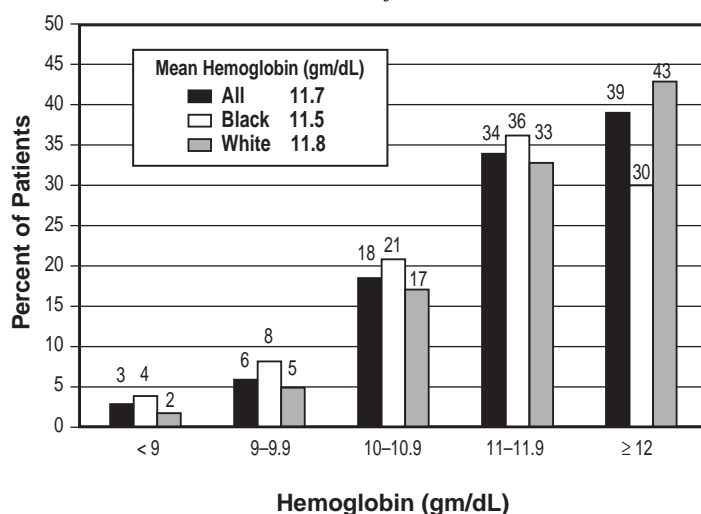


TABLE 20: Mean hemoglobin values (gm/dL) for adult peritoneal dialysis patients, by patient characteristics, October 2000-March 2001. 2001 ESRD CPM Project.

Patient Characteristic	Mean Hemo-globin (gm/dL)	Percent of patients with hemoglobin values (gm/dL)				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
TOTAL	11.7	3	6	18	34	39
GENDER						
Men	11.9	2	5	16	33	45
Women	11.5	3	7	21	35	33
RACE						
American Indian/ Alaska Native	11.3	*	*	*	*	*
Asian/Pacific Islander	11.8	*	*	19	41	34
Black	11.5	4	8	21	36	30
White	11.8	2	5	17	33	43
Other/Unknown	11.8	*	*	*	35	41
ETHNICITY						
Hispanic	11.8	*	*	18	30	43
Non-Hispanic	11.7	3	6	18	35	39
AGE GROUP (years)						
18-44	11.4	7	10	20	31	33
45-54	11.7	*	8	20	33	37
55-64	11.9	*	4	16	35	44
65-74	11.9	*	*	18	36	43
75+	11.8	*	*	12	44	41
DIAGNOSIS						
Diabetes Mellitus	11.7	*	6	19	35	39
Hypertension	11.6	*	8	18	37	34
Glomerulonephritis	11.7	*	*	21	34	38
Other/Unknown	11.8	3	7	16	30	44
DURATION of DIALYSIS (years)						
< 0.5	11.8	*	5	14	35	44
0.5-0.9	11.7	*	7	20	38	33
1.0-1.9	11.7	*	5	22	30	41
2.0+	11.6	3	7	18	35	37
MEAN SERUM ALBUMIN						
≥ 3.5/3.2 (BCG/BCP) [^]	11.9	2	5	14	35	44
< 3.5/3.2 (BCG/BCP)	11.5	4	8	24	32	33
MEAN WEEKLY CREATININE CLEARANCE (L/WEEK/1.73m²)						
≥60	11.8	*	5	16	34	43
<60	11.6	4	7	21	35	34

Note: Percentages may not add up to 100% due to rounding.

[^]BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

*Value suppressed because n ≤ 10.

The average (\pm SD) transferrin saturation for the patients in this sample was 28.6%, (\pm 10.4%) and 81% of patients had mean transferrin saturation \geq 20%. The average (\pm SD) serum ferritin concentration for patients in this sample was 393 ng/mL (\pm 385), with 82% of patients having a mean serum ferritin concentration \geq 100 ng/mL. 72 patients (5% of patients) had both a mean transferrin saturation $<$ 20% and a mean serum ferritin concentration $<$ 100 ng/mL.

88% of the patients in the sample for analysis were prescribed Epoetin during the six month study period. Epoetin was prescribed 97% of the time when the hemoglobin values were $<$ 9 gm/dL, 95% of the time when the hemoglobin values were between 9-9.9 gm/dL, 99% of the time when hemoglobin values were between 10-10.9 gm/dL, 93% of the time when the hemoglobin values were between 11-11.9 gm/dL, and 76% of the time when hemoglobin values were \geq 12 gm/dL.

The prescribed route of administration of Epoetin was collected again this study period. Within the subset of patients who were prescribed Epoetin, 98% were prescribed Epoetin by the SC route; 5% were prescribed Epoetin by the IV route (groups not mutually exclusive). The mean (\pm SD) Epoetin dose for patients prescribed Epoetin by the SC route was 51.6 units/kg/dose (\pm 41.6 units/kg/dose); by the IV route was 66.7 units/kg/dose (\pm 33.2 units/kg/dose).

Iron use was assessed during this study period. Iron by either the oral or IV route was prescribed at least once during the six months for 67% of the patients in this sample, and three times over the six-month period for 45% of the patients. Of the patients prescribed iron, 86% were prescribed oral iron and 23% were prescribed IV iron (not mutually exclusive categories). Among those patients with mean transferrin saturation $<$ 20% and mean serum ferritin concentration $<$ 100 ng/mL (n=72), 82% were prescribed either oral or IV iron at least once during the six months, and 60% received some iron three times over the six month study period. 17% of these patients were prescribed IV iron at least once during the six-month study period.

3. CPM and Other Findings for October 2000–March 2001 compared to previous study periods

The percent of peritoneal dialysis patients with mean hemoglobin \geq 11 gm/dL increased from 55% to 73% from the 1998 to the 2001 study periods (FIGURE 10). This improvement was noted for both Black patients (from 38% to 67%) and for White patients (63% to 76%). The average (\pm SD) hemoglobin increased from 11.6 gm/dL (\pm 1.4 gm/dL) during the 2000 study period to 11.7 gm/dL (\pm 1.4 gm/dL) during the 2001 study period (FIGURE 11). The distributions of mean hemoglobin values over these three study periods were not significantly different by modality (CAPD vs. cycler).

The percent of adult (aged \geq 18 years) peritoneal dialysis patients with mean hemoglobin $<$ 10 gm/dL decreased from 18% in the 1998 study period to 9% in the 2001 study period (FIGURE 58).

The distributions of mean transferrin saturation values (%) and mean serum ferritin concentrations (ng/mL) were similar for the November 1996–April 1997 through the October 2000–March 2001 study periods.

Figure 59 depicts the trend in Epoetin dosing from the 1998 study period to the 2001 study period, with an increasing mean Epoetin dose (units/kg/dose) for patients prescribed Epoetin in most hemoglobin categories from the 1998 to the 2001 study periods. Route of administration information revealed that IV doses were generally larger than SC doses (data not displayed due to small cell sizes).

Figure 60 shows the percent of patients prescribed Epoetin by hemoglobin category for study periods 1998 through 2001.

Figure 58: Percent of adult peritoneal dialysis patients with mean hemoglobin < 10 gm/dL, by race, October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.

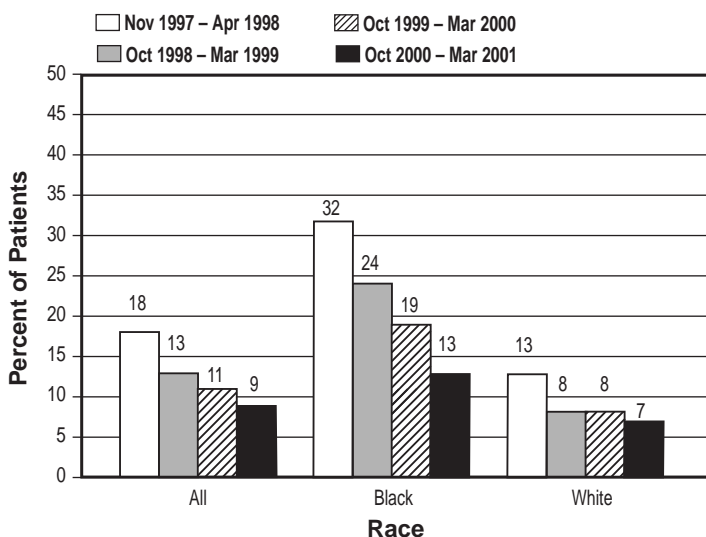


Figure 59: Mean Epoetin dose (units/kg) by hemoglobin category for adult peritoneal dialysis patients prescribed Epoetin October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.

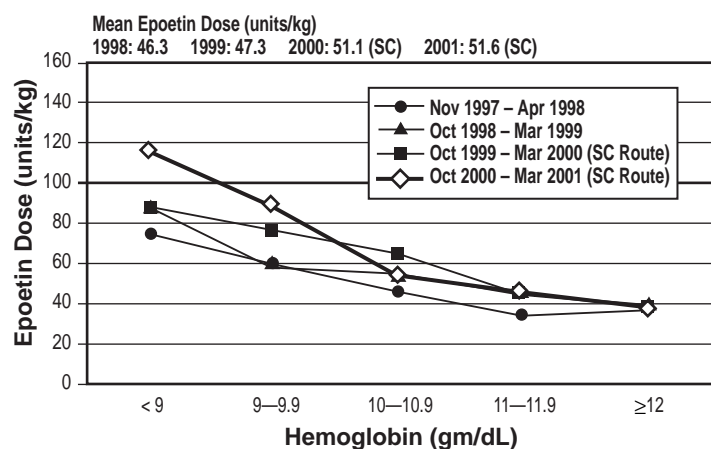
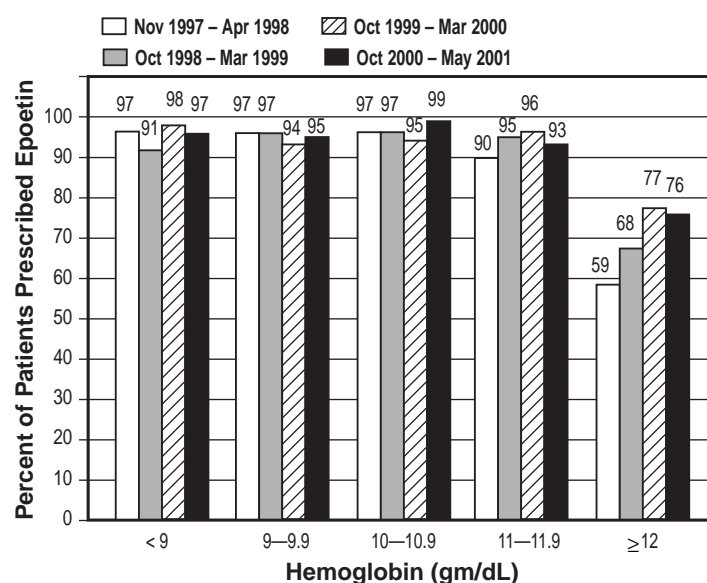


Figure 60: Percent of adult peritoneal dialysis patients who were prescribed Epoetin by hemoglobin category, October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project



C. SERUM ALBUMIN

1. Findings for October 2000–March 2001

The mean (\pm SD) serum albumin value for peritoneal dialysis patients whose value was determined by the BCG method ($n=1,139$) was 3.5 gm/dL (± 0.5 gm/dL) and by the BCP method ($n=191$) was 3.2 gm/dL (± 0.5 gm/dL). “Adequate” serum albumin was defined for this report as ≥ 3.5 gm/dL (BCG) or ≥ 3.2 gm/dL (BCP). “Optimal” serum albumin was defined as ≥ 4.0 gm/dL (BCG) or ≥ 3.7 gm/dL (BCP). Nationally, 14% of patients had a mean serum albumin ≥ 4.0 (BCG) or ≥ 3.7 gm/dL (BCP). 56% of patients had a mean serum albumin ≥ 3.5 gm/dL by the BCG or ≥ 3.2 gm/dL by the BCP method.

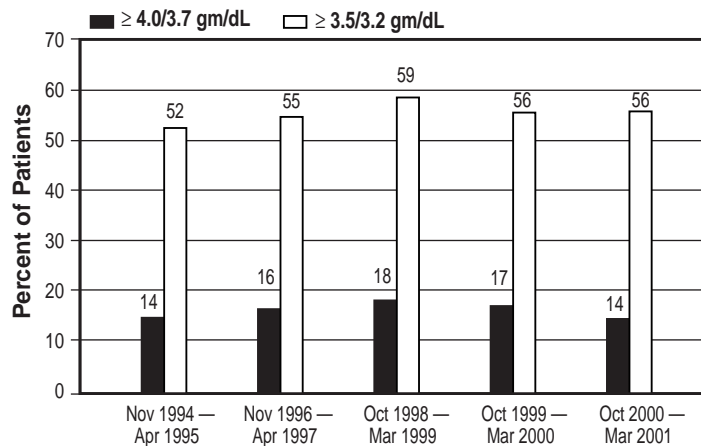
The percent of patients with mean serum albumin defined as either “adequate” or “optimal” by gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters is shown in Table 21. The percent of patients with “optimal” mean serum albumin tended to be higher for men compared to women, for patients 18–44 years compared to older patients, and for patients with causes of their ESRD other than diabetes mellitus compared to patients with diabetes mellitus as the cause. (TABLE 21).

2. Findings for October 2000–March 2001 compared to previous study periods

There was no clinically important change or improvement in the proportion of adult peritoneal dialysis patients achieving either “adequate” or “optimal” mean serum albumin levels from the 1995 study period to the 2001 study period.

Figure 61 shows the percent of patients with mean serum albumin ≥ 4.0 (BCG) method or ≥ 3.7 gm/dL (BCP) method and the percent of patients with mean serum albumin ≥ 3.5 gm/dL (BCG) method or ≥ 3.2 gm/dL (BCP) method during the 2001 study period compared to previous study periods.

Figure 61: Percent of adult peritoneal dialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)* and $\geq 3.5/3.2$ gm/dL (BCG/BCP), October 2000–March 2001 compared to previous study periods. 2001 ESRD CPM Project.



*Note: BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

TABLE 21: Percent of adult peritoneal dialysis patients with mean serum albumin values $\geq 4.0/3.7$ gm/dL (BCG/BCP)^ and $\geq 3.5/3.2$ gm/dL (BCG/BCP) in the US, by patient characteristics, October 2000–March 2001. 2001 ESRD CPM Project.

Patient Characteristic	Percent of Patients with Mean Serum Albumin $\geq 4.0/3.7$ gm/dL	Percent of Patients with Mean Serum Albumin $\geq 3.5/3.2$ gm/dL
TOTAL	14	56
GENDER		
Men	17	60
Women	11	53
RACE		
American Indian/Alaska Native	*	*
Asian/Pacific Islander	22	75
Black	15	54
White	12	56
Other/Unknown	19	52
ETHNICITY		
Hispanic	18	60
Non-Hispanic	13	56
AGE GROUP (years)		
18-44	23	63
45-54	15	59
55-64	10	56
65-74	7	49
75+	*	44
DIAGNOSIS		
Diabetes mellitus	9	47
Hypertension	16	59
Glomerulonephritis	19	68
Other/Unknown	15	59
DURATION of DIALYSIS (years)		
< 0.5	14	53
0.5-0.9	14	60
1.0-1.9	15	58
2.0+	13	56
MEAN Hgb		
≥ 11 gm/dL	15	61
< 11 gm/dL	11	43
MEAN WEEKLY CREATININE CLEARANCE (L/WEEK/1.73m²)		
≥ 60	13	57
< 60	15	55

^ BCG/BCP = bromcresol green/bromcresol purple laboratory methods.

* Value suppressed because $n \leq 10$.

V. PEDIATRIC IN-CENTER HEMODIALYSIS PATIENTS

All patients aged ≥ 12 and < 18 years identified as receiving in-center hemodialysis on December 31, 2000 were included in this study (n=516). 435 patients (84%) of this group met the case definition and were included in the sample for analysis. (See footnote to Table 5 on page 19 for case definition).

At this time, CPMs have not been developed for the pediatric age group. Therefore, the pediatric analysis is presented differently from the adult analysis.

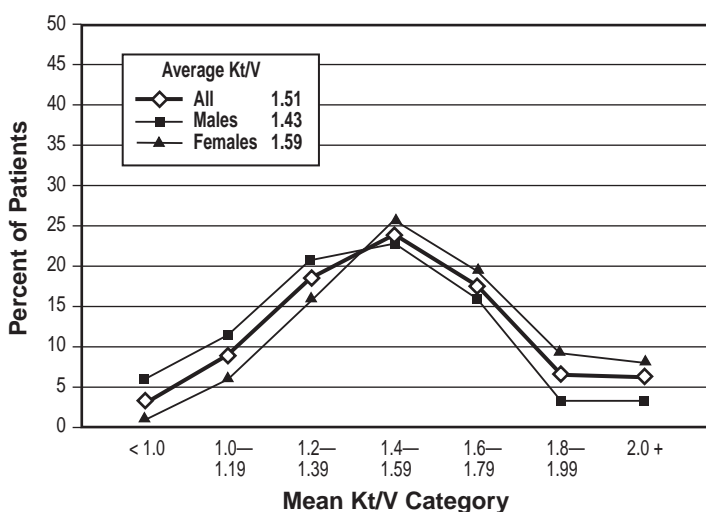
This section describes the findings for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients for core indicators related to adequacy of hemodialysis, vascular access, anemia management and serum albumin. Each subsection is further broken down into two parts: (1) national findings for selected core indicators for October-December 2000; (2) a comparison of core indicator results or findings for October-December 2000 and the previous study period (October-December 1999).

A. ADEQUACY OF HEMODIALYSIS

1. Findings for October-December 2000

The percent of patients in the sample for analysis with at least one calculated Kt/V measure available (n=372) who received adequate hemodialysis, (defined as a mean Kt/V ≥ 1.2 , approximately equivalent to URR $\geq 65\%$ [2]) in the last quarter of 2000 was 85%. The mean (\pm SD) delivered calculated Kt/V of all pediatric in-center hemodialysis patients in the sample for analysis in the last quarter of 2000 was 1.51 (± 0.33) (FIGURE 62). The distribution of Kt/V values for these patients is shown in Figure 62. Kt/V was calculated using the Daugirdas II method; one blood sample was obtained post-dialysis reflecting a single pool distribution (23). The mean (\pm SD) delivered calculated URR for this population was 70.9% ($\pm 7.4\%$). 82% of patients had a

Figure 62: Distribution of mean calculated delivered Kt/V values for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients, by gender, October-December 2000. 2001 ESRD CPM Project.



mean delivered calculated URR $\geq 65\%$.

The mean Kt/V and the percent of patients with mean Kt/V ≥ 1.2 for gender, race, ethnicity, age, diagnosis, duration of dialysis, quintile of post-dialysis body weight, access type, and mean hemoglobin and serum albumin categories are shown in

TABLE 22: Mean calculated delivered Kt/V and percent of pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients with mean Kt/V ≥ 1.2 , by patient characteristics, October-December 2000. 2001 ESRD CPM Project.

Patient Characteristics	Mean Kt/V	% Kt/V ≥ 1.2
TOTAL	1.51	85
GENDER		
Males	1.43	80
Females	1.59	91
RACE		
American Indian/Alaska Native	*	*
Asian/Pacific Islander	*	*
Black	1.42	78
White	1.57	89
Other/Unknown	1.57	93
ETHNICITY		
Hispanic	1.55	90
Non-Hispanic	1.49	84
AGE GROUP (years)		
12 to 15	1.50	84
16 to < 18	1.51	85
DIAGNOSIS		
Congenital-Urologic	1.53	90
Other Causes Combined	1.50	78
DURATION of DIALYSIS (years)		
< 0.5	1.37	64
0.5-0.9	1.45	77
1.0-1.9	1.47	92
2.0+	1.62	93
QUINTILE POST-DIALYSIS BODY WEIGHT (kg)		
32.4-40.7	1.57	91
40.8-47.1	1.66	96
47.2-54.8	1.49	85
54.9-66.9	1.45	79
67.0-181.1	1.38	73
ACCESS TYPE		
AV Fistula	1.53	87
AV Graft	1.61	92
Catheter	1.43	79
MEAN HGB		
≥ 11 gm/dL	1.53	88
< 11 gm/dL	1.46	79
MEAN SERUM ALBUMIN		
$\geq 3.5/3.2$ (BCG/BCP) [^]	1.50	85
< 3.5/3.2 (BCG/BCP)	1.54	86

*Value suppressed because n ≤ 10 .

[^]BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

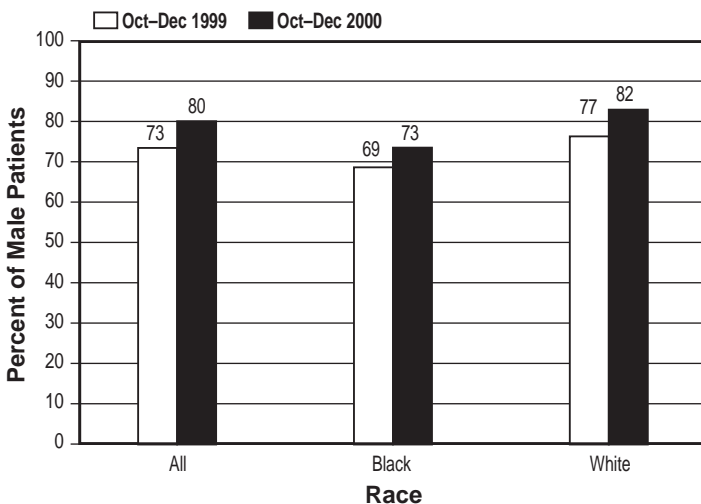
Table 22. The percent of patients receiving hemodialysis with a mean Kt/V ≥ 1.2 was higher for females than for males, for patients in the lowest quintiles of post-dialysis body weight compared to those patients in the highest quartile, and for patients dialyzing six months or longer than for patients dialyzing less than six months (TABLE 22). A larger percent of patients dialyzed with an AV fistula or an AV graft compared to those with a catheter had a mean Kt/V ≥ 1.2 (87% and 92% vs. 79%, respectively). A higher percent of patients with a mean hemoglobin ≥ 11 gm/dL had a mean Kt/V ≥ 1.2 compared to patients with a mean hemoglobin < 11 gm/dL (88% vs. 79%, respectively).

The mean (\pm SD) time spent on dialysis per dialysis session was 208 minutes (\pm 28 minutes). The mean time spent on dialysis was longer for patients aged 16 to < 18 years compared to patients aged 12 to 15 years (210 minutes vs. 205 minutes), for patients dialyzing two or more years compared to patients dialyzing less than six months (211 minutes vs. 206 minutes), for patients in the highest quartile of post-dialysis body weight compared to those patients in the lowest quartile (219 minutes vs. 199 minutes) and for patients dialyzed with an AV graft compared to those patients with an AV fistula or catheter access (214 minutes vs. 207 minutes and 205 minutes, respectively).

2. Findings for October-December 2000 compared to October-December 1999

433/486 (89%) of patients ≥ 12 and < 18 years identified as receiving in-center hemodialysis as of December 31, 1999 were included in the 2000 study year's sample for analysis. 435/516 (84%) of patients ≥ 12 and < 18 years identified as receiving in-center hemodialysis as of December 31, 2000 were included in the 2001 study year's sample for analysis. 188/435 (43%) of patients in the 2001 study year's sample for analysis were also present in the 2000 study year's sample for analysis.

Figure 63: Percent of pediatric (aged ≥ 12 and < 18 years) male in-center hemodialysis patients with mean calculated delivered Kt/V ≥ 1.2 , by race, October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.



The average (\pm SD) delivered Kt/V increased from 1.47 (\pm 0.38) in October-December 1999 to 1.51 (\pm 0.33) in October-December 2000 (FIGURE 12). The percent of patients receiving dialysis with a mean delivered Kt/V ≥ 1.2 increased from 79% in late 1999 to 85% in late 2000. This improvement occurred for both males and females and for White and Black patients (FIGURES 63 and 64).

There was very little change in dialysis session length from late 1999 to late 2000 (FIGURE 65).

Figure 64: Percent of pediatric (aged ≥ 12 and < 18 years) female in-center hemodialysis patients with mean calculated delivered Kt/V ≥ 1.2 , by race, October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.

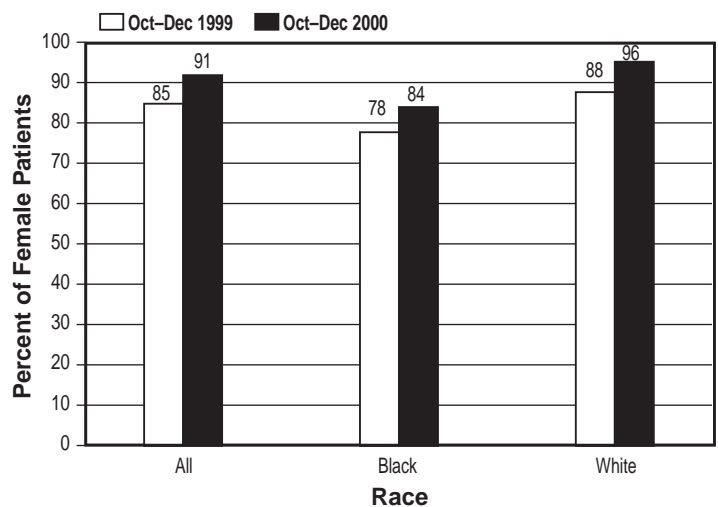
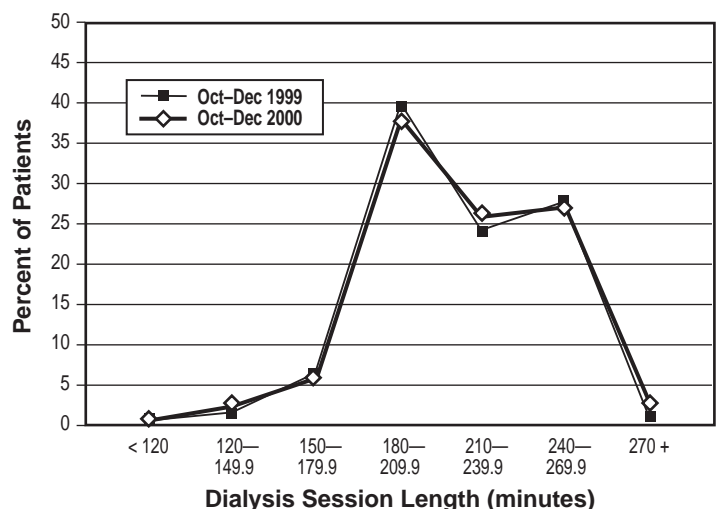


Figure 65: Distribution of mean dialysis session length (minutes) for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients, October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.



B. VASCULAR ACCESS

1. Findings for October-December 2000

31% of patients were dialyzed with an AV fistula (AVF), 24% with an AV graft, and 45% with a catheter during October-December 2000 (FIGURE 13). More males, Whites, and patients aged 16 to < 18 years were dialyzed with an AVF compared to females, Blacks, and patients aged 12 to 15 years (TABLE 23).

TABLE 23: Vascular access type for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients, by selected patient characteristics, October-December 2000. 2001 ESRD CPM Project.

Patient Characteristics	Percent of Patients with		
	AV Fistula	AV Graft	Catheter
TOTAL	31	24	45
GENDER			
Males	39	25	36
Females	22	24	55
RACE			
American Indian/ Alaska Native	*	*	*
Asian/Pacific Islander	*	*	*
Black	26	32	42
White	34	19	47
Other/Unknown	*	*	59
ETHNICITY			
Hispanic	36	18	47
Non-Hispanic	30	26	43
AGE GROUP (years)			
12 to 15	25	23	52
16 to < 18	36	26	38
DIAGNOSIS			
Congenital-Urologic	26	28	47
Other Causes Combined	30	25	45
DURATION of DIALYSIS (years)			
< 0.5	*	*	79
0.5-0.9	40	*	49
1.0-1.9	35	22	43
2.0+	34	36	30

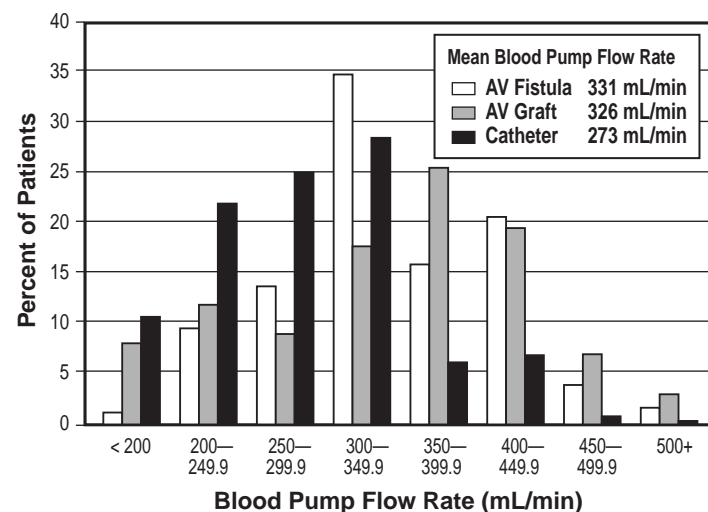
NOTE: Percentages may not add up to 100% due to rounding.

*Value suppressed because $n \leq 10$.

The mean (\pm SD) delivered blood pump flow rate 60 minutes into the dialysis session was 331 mL/min (\pm 74.3 mL/min) for patients dialyzed with an AVF, 326 mL/min (\pm 91.5 mL/min) for patients dialyzed with an AV graft, and 273 mL/min (\pm 70.5 mL/min) for patients with a catheter access during October-December 2000 (FIGURE 66).

195 (45%) of patients had a catheter as their current access in late 2000. The most common reasons for catheter placement included: no fistula or graft created (42%) and fistula or graft was maturing, not ready to cannulate (17%) (TABLE 24). 5% of patients were not candidates for fistula or graft placement as all sites had been exhausted.

Figure 66: Distribution of mean delivered blood pump flow rates 60 minutes into the dialysis session for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients by access type, October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.



NOTE: Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (24). This is particularly true for catheters where differences between delivered and prescribed blood flow to the dialyzer of 25% or more may exist at prescribed blood pump flow rates of 400 mL/min or more (25).

Table 24: Reasons for catheter placement in pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients on their last hemodialysis session during October-December 2000. 2001 ESRD CPM Project.

Reason	n	(%)
TOTAL	195	(100)
No fistula or graft surgically created in this patient's body at this time	82	(42)
Fistula or graft maturing, not ready to cannulate	33	(17)
Temporary interruption of fistula or graft due to clotting or revisions	16	(8)
Renal transplantation scheduled	16	(8)
Patient size too small for AV fistula or graft	14	(7)
All fistula or graft sites in this patient's body have been exhausted	10	(5)
Peripheral vascular disease	0	(0)
Other	24	(12)

NOTE: Percentages may not add up to 100% due to rounding.

41% of patients (98/240) with an AVF or an AV graft had their access routinely monitored for stenosis. (See Appendix 1 for a complete description of the types of stenosis monitoring.) Within this subset of patients, 47% were monitored with dynamic venous pressure, 21% with the Dilution Technique, 13% with static venous pressure, 10% with Color-Flow Doppler, and 19% had other types of monitoring (groups not mutually exclusive).

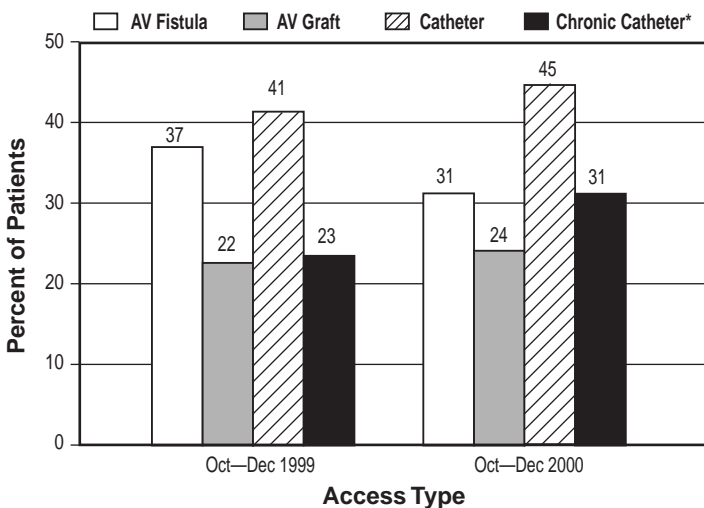
31% of patients (n=134) were dialyzed with a chronic catheter, defined as the continuous use of a catheter 90 days or longer, during October-December 2000.

2. Findings for October-December 2000 compared to October-December 1999

A lower percent of patients was dialyzed with an AVF in late 2000 compared to late 1999 (31% vs. 37%, respectively) (FIGURE 67). A higher percent of patients was dialyzed with a catheter in late 2000 compared to late 1999 (45% vs. 41%, respectively).

23% of patients were dialyzed with a chronic catheter continuously for 90 days or longer during October-December 1999 and 31% during October-December 2000 (FIGURE 67).

Figure 67: Vascular access type for pediatric (aged ≥ 12 and < 18 years) in-center pediatric patients, October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.



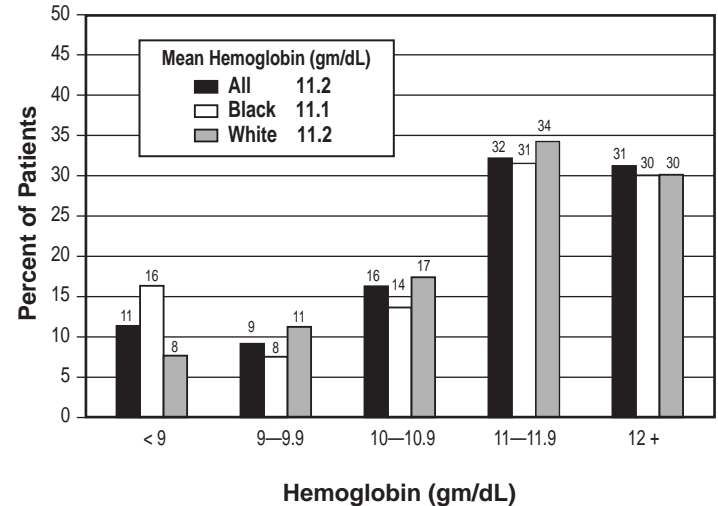
*Chronic catheter use defined as continuous catheter use 90 days or longer.

C. ANEMIA MANAGEMENT

1. Findings for October-December 2000

The distributions of mean hemoglobin values for all patients, and by race, are shown in Figure 68. The mean (\pm SD) hemoglobin value for all patients was 11.2 gm/dL (\pm 1.6 gm/dL). The mean hemoglobin values and distribution of hemoglobin values by gender, race, ethnicity, age, diagnosis, duration of dialysis, access type, and mean Kt/V and serum albumin levels are shown in Table 25. The mean hemoglobin value was significantly lower for patients dialyzing less than six months compared to patients dialyzing six months or longer. Patients with a catheter as their current access had significantly lower mean hemoglobin values compared to patients with either an AV fistula or an AV graft. Patients with higher mean delivered Kt/V values and higher mean serum albumin values also had significantly higher mean hemoglobin values (TABLE 25).

Figure 68: Distribution of mean hemoglobin values (gm/dL) for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients, by race, October-December 2000. 2001 ESRD CPM Project.



The percent of patients with mean hemoglobin < 9 gm/dL was 11%. The percent of patients with mean hemoglobin < 10 gm/dL was 20%. The prevalence of patients with mean hemoglobin < 10 gm/dL was higher in patients dialyzing less than six months compared to those patients dialyzing six months or longer (39% vs. 17%, respectively), and higher in patients with a catheter access compared to patients dialyzed with either an AV fistula or an AV graft. A higher percent of patients with mean Kt/V < 1.2 compared to patients with higher mean Kt/V values had a mean hemoglobin < 10 gm/dL. A higher percent of patients with a mean serum albumin $< 3.5/3.2$ gm/dL (BCG/BCP) compared to patients with higher serum albumin values had a mean hemoglobin < 10 gm/dL.

TABLE 25: Mean hemoglobin values (gm/dL) and distribution of hemoglobin values for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients, by patient characteristics, October-December 2000, 2001 ESRD CPM Project.

Patient Characteristic	Mean Hemo-globin (gm/dL)	Percent of patients with hemoglobin values (gm/dL)				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
TOTAL	11.2	11	9	16	32	31
GENDER						
Males	11.3	10	9	14	33	34
Females	11.1	12	10	19	31	29
RACE						
American Indian/ Alaska Native	*	*	*	*	*	*
Asian/Pacific Islander	12.0	*	*	*	*	*
Black	11.1	16	8	14	31	30
White	11.2	8	11	17	34	30
Other/Unknown	11.5	*	*	*	*	38
ETHNICITY						
Hispanic	11.3	*	12	14	35	33
Non-Hispanic	11.2	13	8	17	32	30
AGE GROUP (years)						
12 to 15	11.1	11	12	18	31	27
16 to < 18	11.3	11	7	14	33	35
DIAGNOSIS						
Congenital- Urologic	11.2	10	11	18	38	24
Other Causes Combined	11.1	13	10	16	28	34
DURATION of DIALYSIS (years)						
< 0.5	10.3	24	15	28	17	17
0.5-0.9	11.6	*	*	*	45	34
1.0-1.9	11.3	*	*	13	26	40
2.0+	11.3	9	9	15	36	31
ACCESS TYPE						
AV Fistula	11.8	*	*	12	37	43
AV Graft	11.2	12	*	13	35	32
Catheter	10.8	16	13	21	27	23
MEAN Kt/V						
≥ 1.2	11.4	9	8	16	33	34
< 1.2	10.7	19	*	*	30	21
MEAN SERUM ALBUMIN						
$\geq 3.5/3.2$ gm/dL (BCG/BCP) [^]	11.4	9	7	16	35	34
$< 3.5/3.2$ gm/dL (BCG/BCP)	10.3	26	20	17	17	20

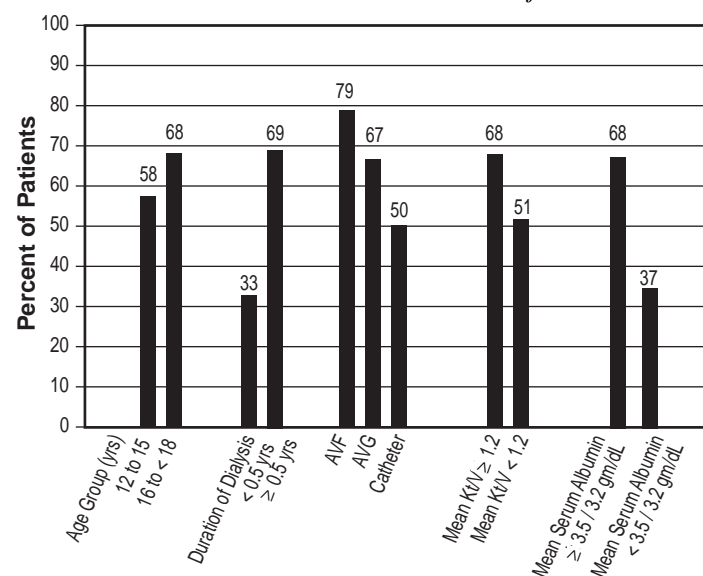
* Value suppressed because $n \leq 10$.

[^] BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

Note: Percentages may not add up to 100% due to rounding.

63% of patients had a mean hemoglobin ≥ 11 gm/dL. The percent of patients with mean hemoglobin ≥ 11 gm/dL by selected patient characteristics is shown in Figure 69. A higher percent of patients aged 16 to < 18 years, patients dialyzing six months or longer, with an AV fistula or an AV graft as their vascular access, mean Kt/V ≥ 1.2 , and mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP) achieved a mean hemoglobin ≥ 11 gm/dL compared to patients aged 12 to 15 years, patients dialyzing less than six months, patients with a catheter access, a mean Kt/V < 1.2 and mean serum albumin $< 3.5/3.2$ gm/dL (BCG/BCP).

Figure 69: Percent of pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by selected patient characteristics and clinical parameters, October-December 2000, 2001 ESRD CPM Project.



97% of patients were prescribed Epoetin during the study period. Of the patients prescribed Epoetin, 91% were prescribed Epoetin by the IV route; and 9% by the SC route (groups not mutually exclusive). The mean (\pm SD) Epoetin dose for patients prescribed Epoetin by the IV route was 96.4 units/kg/ dose (± 72.4 units/kg/dose); by the SC route, 77.3 units/kg/dose (± 63.1 units/kg/dose).

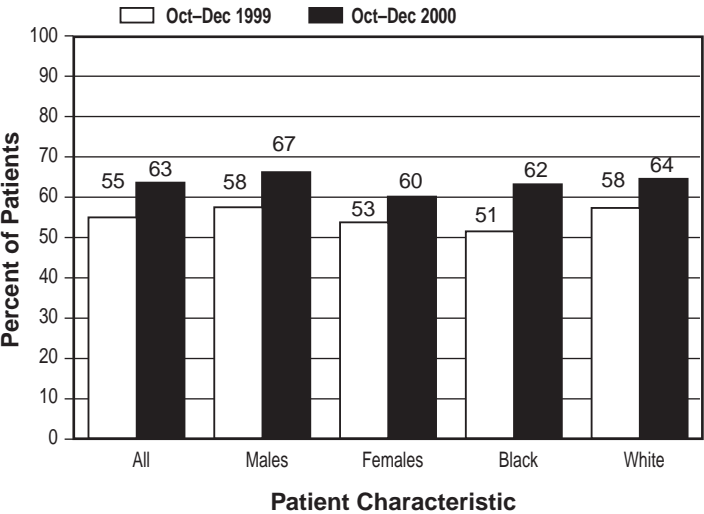
The mean (\pm SD) transferrin saturation for these patients was 29.0% ($\pm 14.2\%$). 74% of patients had a mean transferrin saturation $\geq 20\%$. The mean (\pm SD) serum ferritin concentration was 362 ng/mL (± 341 ng/mL). 75% of patients had a mean serum ferritin concentration ≥ 100 ng/mL.

78% of patients were prescribed either IV or oral iron at least once during the three month study period. The percent of patients with IV iron prescribed was 62%. For the subset of patients with both mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL ($n=39$ or 9% of patients), only 59% were prescribed IV iron at least once during the three month study period.

2. Findings for October-December 2000 compared to October-December 1999

The average (\pm SD) hemoglobin from late 1999 to late 2000 increased from 11.0 gm/dL (\pm 1.6 gm/dL) to 11.2 gm/dL (\pm 1.6 gm/dL) (FIGURE 14). The percent of patients with a mean hemoglobin \geq 11 gm/dL increased from 55% to 63% (FIGURE 70). This improvement occurred for both male and female patients and for Whites and Blacks (FIGURE 70).

Figure 70: Percent of pediatric (aged \geq 12 and < 18 years) in-center hemodialysis patients with mean hemoglobin \geq 11 gm/dL, by gender and race, October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.

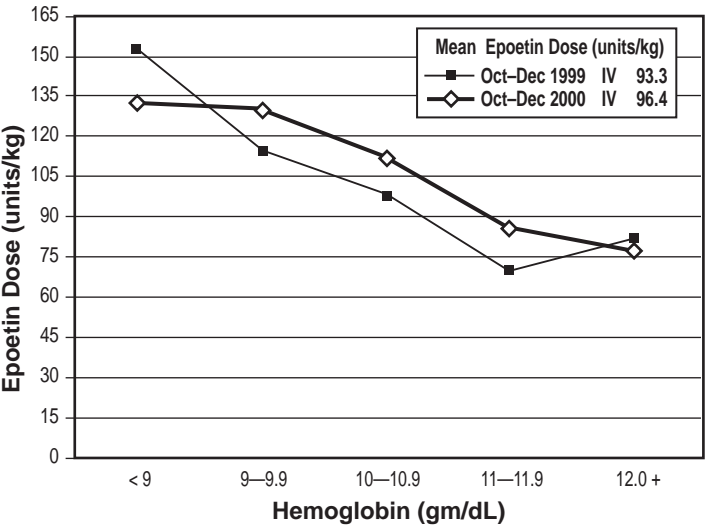


In addition to the improvement in the percent of patients with mean hemoglobin \geq 11 gm/dL, there was also a decrease in the percent of patients with mean hemoglobin < 10 gm/dL. In October-December 1999, 26% of Black patients and 21% of White patients had a mean hemoglobin < 10 gm/dL, while in October-December 2000, 24% of Black patients and 19% of White patients had a mean hemoglobin < 10 gm/dL.

Figure 71 depicts the trend for increasing prescribed Epoetin dosing (units/kg/dose) from late 1999 to late 2000. Prescribed SC Epoetin doses were lower than the prescribed IV Epoetin doses at most hemoglobin categories examined.

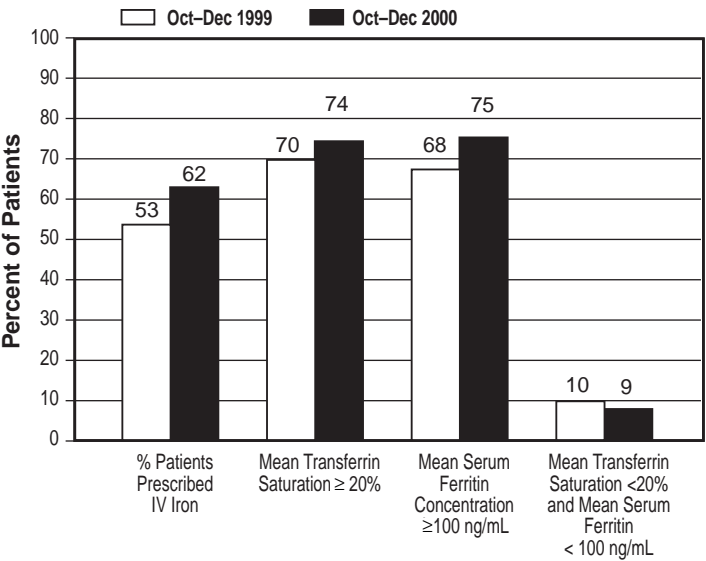
Iron management for pediatric patients improved over the two study periods (FIGURE 72). 53% of patients were prescribed IV iron in late 1999 compared to 62% in late 2000. Within the subgroup of patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 38% of patients were prescribed IV iron at least once over the three month study period in late 1999, compared to 59% in late 2000.

Figure 71: Mean prescribed IV Epoetin dose (units/kg) for pediatric (aged \geq 12 and < 18 years) in-center hemodialysis patients, by hemoglobin category. October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.



NOTE: SC dose distribution not displayed due to small number of patients.

Figure 72: Iron management parameters for pediatric (aged \geq 12 and < 18 years) in-center hemodialysis patients, October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.



D. SERUM ALBUMIN

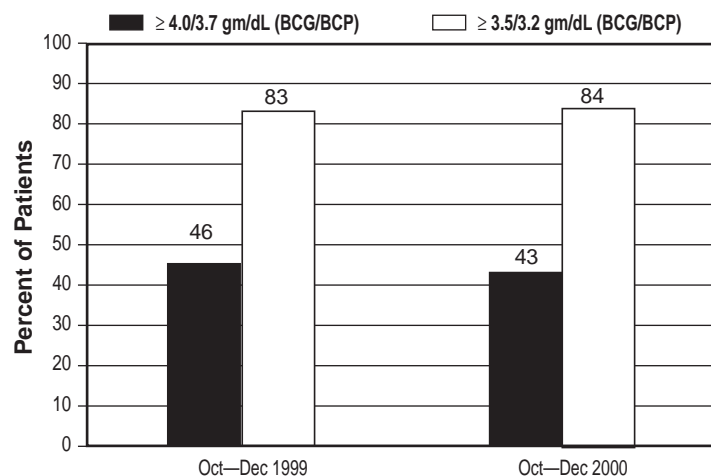
1. Findings for October-December 2000

The mean (\pm SD) serum albumin value for pediatric patients whose value was determined by the BCG method (n=346) was 3.8 gm/dL (\pm 0.5) and by the BCP method (n=88) was 3.6 gm/dL (\pm 0.4). "Adequate" serum albumin was defined for this report as \geq 3.5 gm/dL (BCG) or \geq 3.2 gm/dL (BCP). "Optimal" serum albumin was defined as \geq 4.0 gm/dL (BCG) or \geq 3.7 gm/dL (BCP). Nationally, 43% of patients had a mean serum albumin \geq 4.0/3.7 gm/dL (BCG/BCP). 84% of patients had a mean serum albumin \geq 3.5/3.2 gm/dL (BCG/BCP). The percent of patients with mean serum albumin defined as either "adequate" or "optimal" by gender, race, ethnicity, age, diagnosis, duration of dialysis, access type, and mean delivered Kt/V and hemoglobin categories is shown in Table 26. The percent of patients with "optimal" serum albumin tended to be higher for males compared to females, for Hispanics compared to non-Hispanics, and for patients dialyzing six months or longer compared to those patients dialyzing less than six months. Patients with an AV fistula access were more likely to have an "optimal" serum albumin compared to patients dialyzed with either an AV graft or a catheter. A higher percent of patients with mean hemoglobin \geq 11 gm/dL had an "optimal" serum albumin compared to patients with lower mean hemoglobin values (TABLE 26).

2. Findings for October-December 2000 compared to October-December 1999

There was no clinically important change or improvement in the percent of pediatric in-center hemodialysis patients achieving either "adequate" or "optimal" mean serum albumin levels from late 1999 to late 2000 (FIGURE 73).

Figure 73: Percent of pediatric (aged \geq 12 and $<$ 18 years) in-center hemodialysis patients with mean serum albumin \geq 4.0/3.7 gm/dL (BCG/BCP)[^] and \geq 3.5/3.2 gm/dL (BCG/BCP), October-December 2000 compared to the previous study period. 2001 ESRD CPM Project.



[^]BCG/BCP = bromcresol green/bromcresol purple laboratory methods.

TABLE 26: Percent of pediatric (aged \geq 12 and $<$ 18 years) in-center hemodialysis patients with mean serum albumin values \geq 4.0/3.7 gm/dL (BCG/BCP)[^], and \geq 3.5/3.2 gm/dL (BCG/BCP), by patient characteristics, October-December 2000. 2001 ESRD CPM Project.

Patient Characteristics	Percent of Patients with Mean Serum Albumin	
	\geq 4.0/3.7 gm/dL	\geq 3.5/3.2 gm/dL
TOTAL	43	84
GENDER		
Males	49	87
Females	37	80
RACE		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	*	92
Black	38	83
White	47	84
Other/Unknown	53	85
ETHNICITY		
Hispanic	58	90
Non-Hispanic	38	82
AGE GROUP (years)		
12 to 15	43	83
16 to $<$ 18	43	85
DIAGNOSIS		
Congenital-Urologic	42	87
Other Causes Combined	41	78
DURATION of DIALYSIS (years)		
$<$ 0.5	29	67
0.5-0.9	49	89
1.0-1.9	53	85
2.0+	41	88
ACCESS TYPE		
AV Fistula	61	93
AV Graft	34	80
Catheter	36	80
MEAN Kt/V		
\geq 1.2	45	84
$<$ 1.2	46	86
MEAN HEMOGLOBIN		
\geq 11 gm/dL	52	91
$<$ 11 gm/dL	29	73

NOTE: Percentages may not add up to 100% due to rounding.

*Value suppressed because $n \leq 10$.

[^]BCG/BCP = bromcresol green/bromcresol purple laboratory methods.